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INSTITUTO DE CIÊNCIAS BIOMÉDICAS ABEL SALAZAR
UNIVERSIDADE DO PORTO

ACUTE UPPER GASTROINTESTINAL BLEEDING: USING QUALITY DATA FOR OPERATIONAL AND CLINICAL IMPROVEMENT

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À memória do meu pai, pela honradez, verticalidade, coragem e determinação, pelo exemplo do seu caráter e por tudo o que me legou.

À minha mãe, pelo seu incondicional amor e dedicação.

Aos meus irmãos, com os quais comungo de uma fraternidade indestrutível.

Aos meus filhos, a Raquel e o José Maria, os meus grandes amores.

PREFACE

In October 2006, in the north of Portugal, as a result of human and economic constraints, the out-of-hours gastroenterology emergency was reviewed, reorganized and restructured, by allocating in a single endoscopy unit, gastroenterologists from eight hospitals of the district of Oporto. Presenting this data is the product of my five years of work, as responsible for the management of this out-of-hours endoscopy regional center.

Over the years, as healthcare has become more complex, as quality management has evolved, and the organization where I work has made a strong commitment to the process of quality improvement and patient safety, my understanding of what managing quality means has growth as well. My journey began as a quality risk manager, ten years ago. I was not trained to ask questions, sometimes difficult questions, nor to use data to give answers; at that time, clinical indicators and clinical audit were, for me, a complete mystery. After the implementation of the quality department, for which I was responsible from 2006-2009, I quickly realized that quality information, clinical and non-clinical, can and must be used for daily operations; that it all begins with measures which must be integrated into every aspect of care, so that each aspect can be evaluated, understood and improved. I was extremely fortunate that the hospital board believed in quality and contributed their time to ensuring that the institution continuously strived toward excellence; as well, all the professionals with whom I worked, which always enthusiastically engaged in new projects.

As a gastroenterologist, the issues of quality and patient safety, especially in the emergency care setting, continued to challenge me and inspire me personally and professionally. On the other hand, as responsible for the coordination of this emergency regional model, I asked myself: is this system fair in terms of accessibility, safety and costs? The answer, again, was measures.

Although it seems intuitive that many efficiency strategies may lead to cost savings, some quality drives may lead to increased expenditure. My first clinical audit in acute upper gastrointestinal bleeding, demonstrated that a systematic critical analysis at all levels of patient's care was needed. This has raised some crucial questions in my mind which I tried to answer in my research.

I wrote this thesis to fill what I perceived as a critical gap in healthcare services; to understand the value of data and use them in the whole process of care, as the basis for delivering quality care and try to overcome the economic constraints.

It has been an outstanding and extremely rewarding journey.

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Em janeiro de 1989 cheguei pela primeira vez ao Hospital de Santo António onde encontrei o saudoso Dr. Soares de Sousa, com quem tive o privilégio de trabalhar no serviço de medicina. Os seus ensinamentos, as suas palavras de estímulo, a sua amizade, fizeram com que sentisse o Hospital de Santo António como aquele que viria a tornar-se a minha casa de sempre.

Um ano depois integrei o serviço de Gastrenterologia então dirigido pelo Dr. Amílcar Mascarenhas Saraiva, clínico por quem nutro profunda admiração pela forma como sempre me tratou, pelo rigor que era seu apanágio e pela amizade que desde então perdura. Teve um papel muito importante nos primeiros anos da minha formação e por isso lhe devo um enorme tributo de gratidão e apreço.

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As tarefas de que fui incumbida despertaram em mim o gosto e interesse pela gestão do risco clínico e pela importância da qualidade, atributos essenciais da gestão hospitalar de excelência.

Pela amizade com que me distinguiu ao longo destes anos e que sempre procurei retribuir, o meu profundo agradecimento ao Dr. Sollari Allegro que é também para mim e para todos os que o conhecem um edificante exemplo de coragem, força e inesgotável pertinácia.

Uma palavra de fraternal amizade a todos os meus colaboradores no departamento de qualidade que dirigi durante 3 anos.

Foi um trabalho árduo, estimulante, desafiante, em que foi preciso vencer inúmeros obstáculos, mas sempre pautado por um forte espírito de equipa, por um acrisolado sentido de missão e por um entusiasmo contagiante ao serviço da mudança e de uma cultura organizativa moderna, eficiente e humanista.

Cabe aqui também um agradecimento muito especial dirigido ao Prof. Doutor Martins da Silva, cujo convite para ser sua adjunta na direção clínica me fez crescer e entender ainda mais a necessidade de uma governação clínica na qual os médicos devem liderar o processo e assumirem-se como os principais protagonistas da mudança.

Estou igualmente grata à Professora Doutora Suzete Gonçalves, minha coorientadora, e de quem recebi preciosos ensinamentos enquanto discente das suas aulas de economia da saúde no âmbito da pós-graduação em gestão para médicos, o que muito contribuiu para a minha formação e para expandir os horizontes do meu conhecimento.

Ao Professor Doutor Mário Dinis-Ribeiro pelo estímulo constante e pela forma como tem sabido prestigiar a gastroenterologia portuguesa em Portugal e na Europa.

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A toda a minha família, a expressão do meu amor.

LIST OF PUBLISHED OR ACCEPTED FOR PUBLICATION PAPERS

All papers are referred to in the text by the corresponding Roman numeral. The papers are presented in the chronological order of their production:

Order	Description
Paper I	**Pedroto I**, Dinis-Ribeiro M , Ponchon T. Is timely endoscopy the answer for cost-effective management in acute upper gastrointestinal bleeding? Published in Endoscopy 2012; 44(08): 721-722
Paper II	**Pedroto I**, Amaro P, Romãozinho JM. Health systems organization for emergency care. Published in Best Practice & Research Clinical Gastroenterology 27 (2013) 819–827
Paper III	**Pedroto I**, Maia L, Salgueiro P, Teles de Sampaio E, Küttner Magalhães R, Magalhães MJ, Pinto R, Dias C, Dinis-Ribeiro M. Out-of-Hours Endoscopy for Non-Variceal Upper Gastrointestinal Bleeding Accepted for publication in Scandinavian Journal of Gastroenterology Manuscript ID SGAS-2014-0531.R1: proofs revised.

LIST OF ABBREVIATIONS

AUGIB	Acute upper gastrointestinal bleeding
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CHP	Centro Hospitalar do Porto
CIs	Clinical Indicators
CUA	Cost-utility analysis
ED	Emergency department
ED-CHP	Emergency department of Centro Hospitalar do Porto
EGD	Upper endoscopy
ENERGIB	European Study of Nonvariceal upper gastrointestinal bleeding
GBS	Glasgow Blatchford Score
GRS	Global Rating Scale
IOM	Institute of Medicine
NHS	Britain's National Health Service
NVAUGIB	Non-variceal acute upper gastrointestinal bleeding
PDCA	Plan, Do, Check, Act cycle
PUB	Peptic ulcer bleeding
QALYs	Quality-adjusted-life-years
QI	Quality Improvement
URGE	Regional Gastroenterology Emergency
WHO	World Health Organization

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SUMMARY

Measurement of quality is an important area of the healthcare system. But we have to improve the way we look at quality within organizations and to invest in understanding the information across services. This perspective is essential if new models of care are implemented and intend to be successful. In northern Portugal, an out-of-hours endoscopy regional centre was set up in one tertiary trust in Oporto, o Centro Hospitalar do Porto.

Overall, the research discussed in this thesis explored the aspects of non-variceal acute upper gastrointestinal bleeding management in the real-life context of this regionalized emergency healthcare model. During a 3 year period (January 2010 to December 2012), data from consecutive outpatients (n=332) with non-variceal acute upper gastrointestinal bleeding, admitted or transferred, were prospectively collected, analyzed and compared.

The results illustrate the model's effectiveness and the challenges in understanding and managing the all process of care, necessary for providing high-quality care. Median time to out-of-hours endoscopy was 6h for direct admissions and 7.7h for transferred patients; 90% of the procedures were performed in less than 24h. Rebleeding, 30 day mortality and need for surgery were respectively 9.8%, 7.4% and 6.6% and were not significantly different between the two groups. Age, malignancy and an admission Rockall risk score were predictors of in-hospital mortality, whatever the admission status. In the transferred group, patients with 80 years old or more showed a 11-fold significantly increased risk of rebleeding, than younger patients. Patients transferred with malignancy, a high risk clinical Rockall score and more than 80 years old presented a probability of 30-day mortality, three, six and sixteen times greater. The results emphasize the importance of supporting healthcare providers with tools that enable them to decide in their daily practice whether to comply with standard of care and simultaneously respond to economic constraints.

This regionalization model has overcome the problem of emergency provision and demonstrated equity, safety, efficacy, effectiveness and availability of appropriately trained and experienced endoscopy staff.

We believe this may fit in a larger opportunity to improve processes and outcomes in acute upper gastrointestinal bleeding and other clinical contexts or regions. Nevertheless, it is important to determine, in the near future, the impact of regionalization in the economics of hospitals within the system.

RESUMO

Actualmente é exigido um esforço constante de melhoria contínua da qualidade às organizações de saúde. Mas temos, cada vez mais, de avaliar a qualidade dentro das organizações, melhorando a informação e a comunicação. Esta perspectiva é essencial para que novos modelos de gestão sejam implementados e bem sucedidos. No norte de Portugal, foi criada uma urgência regional noturna de gastrenterologia, no Centro Hospitalar do Porto.

No geral, esta dissertação analisa os cuidados prestados aos doentes no contexto das várias dimensões da qualidade. Este trabalho estuda e discute, comparativamente, os resultados obtidos em doentes admitidos diretamente nesta urgência regional com os de doentes transferidos de outros hospitais que se apresentaram com hemorragia digestiva alta não-varicosa (n = 332). Durante um período de três anos (janeiro de 2010 a dezembro de 2012), foram prospetivamente registados os dados destes doentes.

O tempo mediano para a realização de endoscopia foi de 6h para as admissões diretas e de 7,7h para os doentes transferidos e 90% dos procedimentos foram realizados nas primeiras 24 horas. A recidiva hemorrágica, a mortalidade e a necessidade de cirurgia urgente foram respetivamente de 9,8%, 7,4% e 6,6% e semelhantes nos dois grupos. A idade, a malignidade e o score clínico de Rockall foram preditores de mortalidade hospitalar, independentemente do tipo de admissão. No grupo dos doentes transferidos, os que tinham uma idade igual ou superior a 80 anos apresentaram um risco 11 vezes superior. Os doentes com neoplasia, os portadores de um elevado score de admissão de Rockall e os com mais de 80 anos tinham probabilidade de mortalidade aos 30 dias, três, seis e dezasseis vezes maior. Os resultados enfatizam a necessidade de integração de metodologias e ferramentas da gestão da qualidade na área da saúde, numa perspectiva operacional, capaz de permitir, não só a optimização dos processos mas, simultaneamente, uma gestão mais eficaz dos recursos.

Este modelo de regionalização resolveu o problema da provisão de recursos humanos e demonstrou equidade, segurança e eficiência, com a disponibilidade de uma equipa de endoscopia experiente.

Esta tese, focalizada em aspectos nucleares da gestão da qualidade, alerta para o benefício de uma abordagem integrada de gestão da qualidade na saúde, neste e noutros contextos clínicos ou noutras regiões do País. No entanto, é importante determinar, num futuro próximo, o impacto económico da regionalização nas instituições que integram o modelo.

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CHAPTER I

INTRODUCTION

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CHAPTER I

INTRODUCTION

Ia. Context

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I. INTRODUCTION

Ia. Context

Why is this research important?

Improving the quality of services is now a key requirement within any health institution. It is about making healthcare safer, effective, patient centered, timely, efficient and equitable. In the past decade, there has been a great focus on improving the quality of health services, but the boards are being challenged to respond to the rigor imposed by economic constraints.

Furthermore, acute upper gastrointestinal bleeding (AUGIB) is one of the most common emergency medical admissions for gastroenterology and has a significant inpatient mortality of 10% that has not improved over the last two decades (van Leerdam, Vreeburg et al. 2003; Targownik and Nabalamba 2006; Lanas, Garcia-Rodriguez et al. 2009).

With our ageing population, comes a number of health challenges in this area (Yachimski and Friedman 2008). Although the overall incidence of AUGIB seems to have declined since the 1990s, the studies suggest that people aged more than 60 years constitute an increasing proportion of those presenting with AUGIB (Thomopoulos, Vagenas et al. 2004; Targownik and Nabalamba 2006; Lanas, Garcia-Rodriguez et al. 2009). Also, advanced age has been consistently identified as a risk factor for mortality in patients with AUGIB, in whom the outcome is influenced also by the presence of medical comorbidities, increased prescriptions for these comorbidities and interactions between the two (Cappell and Nadler 1995; Rockall, Logan et al. 1995; Hasselgren, Blomqvist et al. 1998; Hasselgren, Carlsson et al. 1998; Yamaguchi, Yamato et al. 2003; Baradarian, Ramdhaney et al. 2004; Thomopoulos, Vagenas et al. 2004). This calls for a timeliness and coordinated approach from diagnosis to treatment, in order to optimize favorable outcomes.

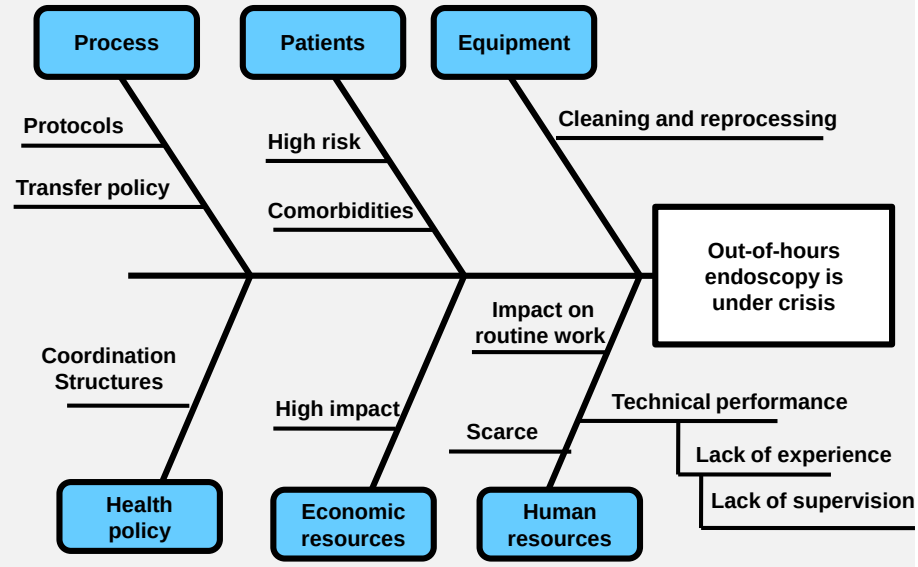
Endoscopy in AUGIB is a time-critical procedure that should be performed in the first 24h (Barkun 2010). The implementation of early discharge policies is an important issue in today´s health care, but, in these cases, necessitates a rapid diagnostic endoscopic service. So, if this procedure is performed early, may avoid expensive and unnecessary

inpatient treatment with early discharge and reduction of the length of stay. However, how urgently endoscopy needs to be done is still debated (Pedroto, Dinis-Ribeiro et al. 2012).

What is lacking in the current knowledge

Some studies have identified serious gaps within the hospital like inadequate out-of hours-service, inappropriate triage and staff shortages in the management of AUGIB (da Silveira, Lam et al. 2006; Hearnshaw, Logan et al. 2010; Jairath, Kahan et al. 2012). But outside factors affecting the hospital must also be taken into account: inadequate access of the general population to specialists; delayed ambulance service; the all structure of the delivery system (da Silveira, Lam et al. 2006). The diagram bellow clarifies the factors discriminated in the studies mentioned above, and draws attention for the need of a systemic approach (figure 1).

Figure 1: Out-of-hours endoscopy is under crisis



This Ishikawa diagram intends to give a visualization of the potential causes of a problem called out-of-hours endoscopy.

So far as we know, there is no information available on the clinical management of AUGIB in relation to the current organization of the emergency health care services in Portugal, namely non-variceal acute upper gastrointestinal bleeding (NVAUGIB), neither a single cause and effect scenario to address timely endoscopy in northern Portugal. And, moreover, there is not a great deal of scientific analysis on these issues.

Paper I and II assess this two issues, from the endoscopy perspective to the organizational level, which can be read at the end of this chapter.

Context of the innovation

AUGIB is a time-critical event, the care of which should be timely, patient-focused and consultant-based; a 24-hours-a-day, 7-days-a week, has the essential requirements for an emergency model of care and the service should be organized around the patient's needs. New models of care should be beneficial to patients and staff, rather than just being considered for purely economic or administrative reasons. But, unlike other clinical areas, cardiac or stroke care, the field of emergency care in gastrointestinal emergencies, currently lacks a uniform set of metrics which informs providers, administrators, and consumers about the status of their care. All of this calls for a coordinated approach and organizational (national, regional or local) models of care. These must become the driving force for organizing, evaluating, and facilitating medical care across the full care cycle. We found no studies directly addressing the causal relationship between all three variables of care: structure, processes and outcomes, although in some, associations between outcomes and resources could be inferred. Our review suggested that more research is needed to establish a robust and effective model of gastroenterology emergency service delivery (Pedroto, Amaro et al. 2013).

In northern Portugal, none of the institutions had sufficient resources to ensure a 24-hour gastroenterology emergency service. In October 2006, an out-of-hours endoscopy regional center was set up (Regional Gastroenterology Emergency-URGE) in one tertiary trust in Oporto covering a population of three million. This is the place where 30 consultant gastroenterologists from eight hospitals and eight nurses from the endoscopy unit are integrated as the gastroenterology emergency team, everyday from 8pm to 8am; they are responsible for handling gastroenterology emergencies, especially those requiring urgent endoscopy.

Although ppopulation-base epidemiology data are important to get insight in the actual healthcare problem, it is vital to understand the current demand, outcomes and causes of NVAUGIB to inform and improve future management of this organizational acute model of care in northern Portugal.

In northern Portugal, the management of NVAUGIB in the past decade was dependent on the organizational structure of each hospital. Until October 2006, endoscopy was

performed within normal working hours only, i.e. usually the next working day after admission. The establishment of a dedicated out-of-hours endoscopy unit gave us the opportunity and clinical material to inquire whether the new model of treatment covers the various dimensions of quality in health care.

CHAPTER I

INTRODUCTION

Ia. Context

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I. INTRODUCTION

Ib. Outline and Aims of the Thesis

AUGIB is defined as acute bleeding into the lumen of the gastrointestinal tract above the ligament of Trietz, typically presenting with haematemesis or melaena. It is the commonest emergency medical admission for gastroenterology, has an overall 30 day case mortality in the range of 2-14%, and is associated with a significant burden on health care resources. AUGIB is commonly categorized as variceal [from oesophageal or gastric varices] or non variceal bleeding. Non variceal bleeding is more common and can be further subdivided by its causes, being the peptic ulcer the most common.

Quality in the health care (chapter IV) setting may be defined as the extent to which a health care service produces a desired outcome. Quality improvement (QI) is now a driving force in health care and is an essential aspect of service delivery at all levels. But, unless we measure, it's difficult to know exactly where we stand, what to improve and whether we have in fact achieved improvement; so, efforts to improve systems or processes must be driven by reliable data.

This thesis investigates, by covering the all process of care, the outcomes of NVAUGIB and the underlying causes and consequences, in the setting of a new regional emergency organizational model by assuming a systems perspective. We thought that this model might offer high availability and quality of care at every stage, as well as continuity between each step of an interconnected treatment process, that would reduce the patient's waiting time for endoscopy, speed up recovery with a multi-disciplinary approach, and manage resources in a more efficient way.

The purpose of the research substantiated in this thesis was to increase the understanding of NVAUGIB in the northern Portugal and the quality of the regional healthcare managing process, by implementing a prospective collection of data and outcome.

To fulfill the purpose of the thesis, four research questions have been posed in the context of the regional model of care. The formulation of the questions was governed by the relevance to understanding and managing NVAUGIB and the potential for healthcare QI.

Research Questions

Research Question 1

The care provided in NVAUGIB was accessible and timely?

Research Question 2

The care provided in NVAUGIB was appropriate and effective?

Research Question 3

The care provided in NVAUGIB was supported by best evidence and practice guidelines?

Research Question 4

The care provided in NVAUGIB was safe and efficient?

CHAPTER I

INTRODUCTION

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I. INTRODUCTION

Ic.Thesis Structure

This thesis is divided into six chapters.

The first chapter starts with a description of the selected research area followed by the purpose and the research questions. These issues fall within the substance of papers I and II, the controversies around endoscopy time frame and a review of emergency models of care in emergency gastroenterology. The thesis structure is presented.

The chapter two is a presentation of the literature review, namely in the management of healthcare quality. Clarifications of the key concepts and previous studies in non-variceal acute upper gastrointestinal bleeding, in order to get a deeper insight of the subject matter can be find in this chapter.

The chapter three explains the methodology and describes the techniques used in the collection and analysis of data.

The chapter that follows contains an analysis of the empirical data followed by its presentation in paper III.

Chapter five discusses whether the aims and objectives of the study were achieved.

A summary and conclusions of the research will be presented, as well as some recommendations for management and future research, in chapter six.

Is timely endoscopy the answer for cost-effective management of acute upper gastrointestinal bleeding?

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Please see related articles from Jairath et al. p. 723, and de Groot et al. p. 731

Endoscopy plays a major role in the management of acute upper gastrointestinal bleeding (UGIB) as it is currently accepted to be an effective procedure for the reduction of the rate of rebleeding, the need for surgery, and mortality [1]. However, because the safety of a very early endoscopy has been questioned and due to the associated organizational needs and related costs, diverse attempts have been made over the years to determine the best combination of peri- and intra-endoscopy procedures ("how"?), "when" to provide endoscopy, and the patients "to whom" endoscopy must be offered to achieve a cost-effective model of healthcare. It seems, however, that there is still room for improvement. In fact, even the group involved in the most recent recommendations for the management of acute nonvariceal UGIB [2] were only able to include the statements "endoscopy should be recommended within 24 hours of presentation for most patients" and "prognostic scales to stratify patients according to their death and rebleeding risks" should be used.

In 2001, a systematic review [3] found only three randomized trials in which early endoscopy was the intervention under study but the studies were considered to be of low methodological quality, with heterogeneous inclusion criteria and definitions of early endoscopy (from prompt to within 24 hours). The authors of the review concluded, based on observational and prospective uncontrolled trials, that in high risk patients (a definition that also varied across studies) rebleeding and surgical rates were improved when early endoscopy was provided but no change to mortality was observed. They recommended well-designed trials to be conducted and since then at least two randomized trials [4, 5] have compared endoscopy undertaken at less than 12 hours with endoscopy at 12–24 hours with no significant reduction in rebleeding, surgical or mortality rates being observed. It seems that any effort to clarify the best time to perform endoscopy is complicated by the variations in routine clinical practice and the type of patients treated. Probably the best evidence will come from studies with very well defined and standard criteria and procedures. Should we move from "the sooner the better" as concluded in 2001 to the concept of "a timely endoscopy" and do we have the studies to answer these questions?

In this issue of *Endoscopy*, Jairath et al. [6] presented the results of a prospective audit in 212 hospitals in the UK. The study addressed whether the time to upper gastrointestinal endoscopy is related to rebleeding, need for surgery, length of hospital stay, and mortality in 4478 patients with acute nonvariceal UGIB. Even though no effect was observed in the mortality or surgery rate, earlier endoscopy did increase the efficiency of care: a substantial reduction in risk-adjusted length of hospital stay and potentially improved control of hemorrhage in higher risk patients were observed, which may support the routine use of early endoscopy with potential savings. This supports previous reports that in all risk groups early endoscopy significantly reduces the length of hospital stay [7]. It was also noted that early endoscopy (sooner than 24 hours) was effective, but in high-risk patients (those who will need endoscopic therapy), an even earlier endoscopy seems to be beneficial in terms of rebleeding. Again, what seems more rational is to argue in favor of an adjustment of the concept of early endoscopy according to patient risk for rebleeding and other outcomes – the concept of "a timely endoscopy."

These kinds of studies with large numbers of patients, if valid, will clarify the inconclusive results from previous single-centered, small or nonrandomized trials. Moreover, they will facilitate discussion of potential drawbacks of studies and of clinical practice reporting, perhaps providing the opportunity for additional studies and further

improvement! In this case, 50 % of the patients underwent endoscopy after 24 hours of bleeding, no clear criteria for blood transfusion were reported, and there appeared to be a potential misuse of resources with 5 % of low-risk lesions (too many?) and only 61 % of high-risk lesions (not enough) being subjected to endoscopic treatment; this perhaps suggests variation in the definitions of risk predictors. Again, current recommendations [1] include diverse suggestions concerning pharmacological and endoscopic methods but no statement relating to the wider management of care in these patients, such as access to healthcare, minimal training, and skill set of emergency teams. As Spiegel concluded in 2001 [2], we also need standards in this setting.

In another contribution to this issue of *Endoscopy*, de Groot et al. [8] present a very important paper on the second part of this treatment concept – timely endoscopy. The authors summarized 16 studies, published from 1987 to 2009, that described diverse scores, all of which considered pre-endoscopic variables and five of which also included endoscopic features, all with the aim of predicting different clinical outcomes after UGIB. Importantly, substantial heterogeneity and the absence of external validation and impact analysis for these scores were noticeable. Different variables were considered, with co-morbidity (11 studies or 17 if liver disease and obesity are included), blood pressure (10 studies), heart rate (5 studies), and age (5 studies) being the most frequently considered among pre-endoscopic parameters. The authors were able to suggest specific scores for different outcomes based on good or high methodological quality, predictive power, and external validation. A score that would work for all outcomes, even if different cut-offs were included, would be welcomed. Adequate derivation and validation in different settings, using "time to endoscopy" as outcome, and all other clinical and organizational outcomes would also need to be considered.

We may therefore conclude that if endoscopy is provided in a timely manner, improvement in all major clinical outcomes and probably savings in the cost of care of patients with acute UGIB could be achieved. Nevertheless, we need more studies in this setting, particularly those that consider the complete process of care, as it is clear that the answer will vary according to the diversity of healthcare settings, including the proportion of high-risk patients coming to emergency care, health providers' awareness of standards of practice, and the associated costs.

Competing interests: None.

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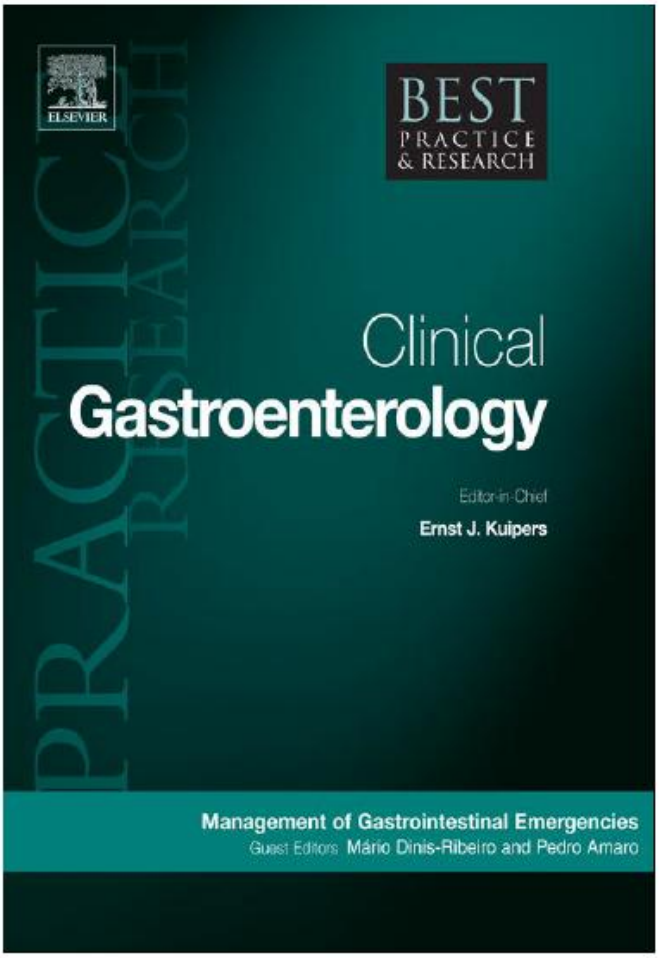

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Health systems organization for emergency care

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ABSTRACT

The increasing number of acute and severe digestive diseases presenting to hospital emergency departments, mainly related with an ageing population, demands an appropriate answer from health systems organization, taking into account the escalating pressure on cost reduction. However, patients expect and deserve a response that is appropriate, effective, efficient and safe. The huge variety of variables which can influence the evolution of such cases warranting intensive monitoring, and the coordination and optimization of a range of human and technical resources involved in the care of these high-risk patients, requires their admission in hospital units with conveniently equipped facilities, as is done for heart attack and stroke patients. Little information of gastroenterology emergencies as a function of structure, processes and outcome is available at the organizational level. Surveys that have been conducted in different countries just assess local treatment outcome and question the organizational structure and existing resources but its impact on the outcome is not clear. Most studies address the problem of upper gastrointestinal bleeding and the out-of-hours endoscopy services in the hospital setting. The demands placed on emergency (part of the overall continuum of care) are obvious, as are the needs for the efficient use of resources and

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processes to improve the quality of care, meaning data must cover the full care cycle. Gastrointestinal emergencies, namely gastrointestinal bleeding, must be incorporated into the overall emergency response as is done for heart attack and stroke. This chapter aims to provide a review of current literature/evidence on organizational health system models towards a better management of gastroenterology emergencies and proposes a research agenda.

The emergency health service

In Europe, unlike in the U.S.A., health care is viewed as a utility with equal access to the whole population, as opposed to a free-market commodity with supply and demand influencing access to care. All European countries have a legal framework of health care delivery for the general population. It is planned and administered centrally by the respective government ministries with a variety of delivery systems. For example, in France and the UK the system is centrally controlled with management directly responsible to the Ministry of Health. In Germany, Italy and Spain the health care delivery system is decentralized and local government bodies have autonomy [1,2]. So, in Europe, because health care is planned and administered by a central body, policies can be implemented universally.

The second edition of Health at a Glance as published by OECD [3] presents the most recent key indicators of health and health systems across 35 countries in Europe. Together, ischaemic heart disease and stroke comprise 60% of all cardiovascular deaths, and caused more than one-fifth of all deaths in EU member states in 2010. There has been progress in the treatment of life-threatening conditions such as heart attack and stroke in all reporting European countries. Mortality rates following hospital admissions for heart attack (acute myocardial infarction, AMI) have fallen by nearly 50% between 2000 and 2009 and for stroke by over 20%. These improvements reflect better acute care and greater access to dedicated stroke units in countries like Denmark and Sweden. Care for AMI has changed dramatically in recent decades [4,5]. Clinical practice guidelines, such as those developed by the European Society of Cardiology, provide clinicians with the best available evidence on how to optimize care. Numerous studies have shown that greater compliance with guidelines improves health outcomes [6,7]. AMI case-fatality rates refer to the percentage of patients who die within 30 days of a hospital admission for AMI. This indicator is influenced by not only the quality of care provided by hospitals but also by differences in hospital transfers, average length of stay, emergency retrieval times and average severity of AMI. Patient-based data, which follow patients in and out of hospitals and across hospitals, are predicted to be a more robust indicator for international comparison than admission-based data, as the latter may bias case-fatality rates downwards if unstable cardiac patients are commonly transferred to tertiary care centers. The AMI case-fatality rate for the ten EU member states reporting data over this period fell by nearly 50% between 2000 and 2009. These substantial improvements also reflect better and more reliable processes of care. Also, the treatment for ischaemic stroke has advanced dramatically over the last decades. Dedicated stroke units were introduced in many countries to facilitate timely and aggressive diagnosis and therapy achieving better survival than usual care [8], although there was a six-fold cross-country difference between the highest and lowest percentage of in-hospital case-fatality for hemorrhagic stroke. In Finland, 6.5% of hemorrhagic stroke admissions lead to death within 30 days, whereas in Belgium the corresponding figure was 38.6%. One potential reason for this is that patients were not systematically transported to hospitals with dedicated stroke units in Belgium so that some patients miss out on optimal care.

In fact, the nature of Emergency Medicine (EM) has changed significantly in recent years with the advent of new treatment options and the availability of more medical technology, such as specialized intravenous thrombolysis in stroke and stent placement in AMI. Many of these are time-critical procedures, leading to greater emphasis on resuscitation, stabilization, investigation and initial management in the Emergency Department (ED). Conditions for which patients were previously admitted and observed are now managed in the ED, allowing for direct discharge without the added cost of inpatient hospitalization. In Europe, in-hospital emergency medical services (IN-H-EMS) refer to all those subsets

of medical institutions and hospitals that have the capacity to deliver uninterrupted emergency care on a 24-hours-a-day, 7-days-a-week basis. All units, departments, wards, etc. that provide continuous care should be considered part of an IN-H-EMS. For instance, a gastroenterology unit staffed by professionals (gastroenterologists and nurses) and providing full-time (24-hours-a-day, 7-days-a-week) specialized care (diagnostics, endoscopy, etc.) should be considered a component of IN-H-EMS. On the other hand, ED crowding is a global problem that has drawn increasing international attention. One of the most significant reported causes of ED crowding is the ageing population and changes in the type of patients presenting to the ED [9]. One study conducted in the UK showed that between 1990 and 2004 the median age of the population increased by ten years [10]. It also showed that in 2004 the proportion of patients presenting to EDs who were 70 years or older was 198% higher than in 1990, and the proportion of patients 90 years or older was 671% higher. In countries such as Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Switzerland and the UK, the general practitioner (GP) acts as a gatekeeper to health services whose role is primary health care provider. Increasing numbers of patients across Europe are bypassing the GP and primary health care system to present to EDs [11].

Practice Points

- Emergency health services must ensure that all patients receive an initial high-quality acute care.
- Emergency activities should seek to build on and not duplicate or replace existing work.
- Interventions must establish coordination and each organization must know what to do.
- Local and national governments and institutions should be involved in planning, implementation and allocating human and financial resources.
- With limited resources, emergency health services planning must be based on the best available information.

Gastroenterology as a component of the emergency health service

A review of the literature published between 1980 and 1998 found few high-quality studies that dealt with the effectiveness of specialized care in general hospitals. However, there is some evidence that patients admitted with gastrointestinal bleeding, acute pancreatitis and acute liver disorders fare better when care is provided by appropriate specialists. The authors found a substantial amount of work detailing guidelines for care, but a distinct paucity of rigorous, evidence-based studies dealing with service provision [12]. The most common medical emergency which has been the subject of recommendations and discussion, both in the clinical context and organizational level, is acute upper gastrointestinal bleeding and emergency endoscopy units. Upper gastrointestinal bleeding, a time-critical event (similar to AMI or stroke) the care of which should be timely, patient-focused and consultant-based, 24-hours-a-day, 7-days-a week, has the essential requirements for an emergency model of care. Nevertheless, little information is available on the clinical management of upper gastrointestinal bleeding in relation to the current organization of the emergency health services. The report on endoscopy services provision in District General Hospitals in the UK [13] dealt with the organization of health care in gastrointestinal bleeding. Most District General Hospital endoscopy budgets did not provide sufficient funding for a 7-days-a-week, 24-hour on-call service by endoscopy nurses. Rota restrictions tend to lead to medical and surgical Consultant Gastroenterologists being called in to deal with these patients, often being required to use sub-standard equipment in operating theatre annexes. There were also difficulties in providing out-of-hours endoscopy nurse cover and an acceptable rota of experienced endoscopists, particularly in smaller District General Hospitals, where the number of patients requiring out-of-hours endoscopy may be as few as one or two per week. One possible solution to minimize this aspect would be to provide a short session at the start of the day (8 am–9 am) for patients admitted during the previous 24 hours. However, this system requires a robust referral procedure; this approach would lead to larger lists on a Monday morning to deal with weekend admissions and difficulties would arise for patients admitted in the early part of the weekend

although some hospitals do have a routine Saturday morning endoscopy list to deal with patients with gastrointestinal haemorrhage admitted on a Friday evening. The authors suggested that GI Endoscopy Units must prospectively audit the true requirement for emergency endoscopy on Saturdays and Sundays, before making formal provision for weekend endoscopy lists. In 2007 the British Society of Gastroenterology published a document [14] on out-of-hours care calling for a reorganization of services to provide for safe care of all gastroenterological emergencies and advising that time should be allocated for emergency out-of-hours endoscopy work – predominantly the management of gastrointestinal haemorrhage; in larger units with skilled endoscopists, emergency cover that is available 24-hours-a-day, 7-daysa week should be the aim. This could be achieved in smaller units only by the continuing dedication of staff working long hours or by units merging in order to provide such 24-hour care. As far as possible, the aim should be to schedule sessions during the week and at weekends to manage patients admitted with acute GI haemorrhage. Such rotas should include all of those with appropriate skills, particularly members of the medical and surgical GI teams.

In fact, the majority of studies looking at delivery of care in acute upper gastrointestinal bleeding have emerged from the UK. The main objectives of the study from Button et al [15] were to establish the incidence of hospital admissions for upper GI bleeding in Wales and case fatality at 30 days following admission, and to investigate whether case fatality was higher for admissions on weekends and public holidays and whether there was an association with factors such as social deprivation, distance from hospital and hospital size. Hospital in-patient and mortality data for 24 421 admissions for upper GI bleeding among 22 299 people in Wales from 1999 to 2007 were included. Rates of endoscopy on the day of admission were lower ($p < 0.001$) for admissions on Saturdays (8.5%) and Sundays (7.4%) than on weekdays (17.5%–20.9%). The median time to endoscopy was higher at weekends. Compared with weekday admissions, case fatality was 13% higher for weekend admissions and 41% higher for admissions on public holidays. Mortality was slightly worse among people resident in the most urban compared with the most rural residences. The distance travelled to hospital affected prognosis adversely. There were large differences in both incidence and case fatality across local authorities. The authors possible explanations for the increased mortality at weekends and on public holidays were: reduced staffing levels; lack of specialist or senior consultant cover; less application of multidisciplinary team care; poor communication; possible delays to endoscopy in some hospitals without out-of-hours services. In fact, even with 24,421 admissions we cannot understand how the full cycle of care is provided and how the services and hospitals are organized but simply raise questions about the processes and structure. The same applies to the findings of North American studies that have also reported increased mortality for admissions at weekends for upper GI bleeding [16].

Data from the Canadian Registry of patients with Upper Gastrointestinal Bleeding and Endoscopy (RUGBE) determined clinical outcomes and explored the roles of endoscopic and pharmacologic therapies in a contemporary real-life setting of patients presenting to community and tertiary care institutions between 1999 and 2002 and established guidelines [17]. According to the Canadian Association of Gastroenterology, almost all gastroenterologists (97%) provide on-call for hospital in-patients, but many (79%) also provide emergency room on-call. Less than half (44%) make themselves available to non-hospitalized patients either by telephone or seeing the patient if required. Of those on-call, the majority (61%) tend to spend up to 120 hours per month on-call, 20% between 121 and 180 hours per month and another 20% spend more than 180 hours per month. The policy in Northern Ireland is to include gastroenterologists, intensive care physicians, surgeons, and radiologists at an early stage of the admission and decision-making process to optimize care of potentially ill patients [18].

In June 2012, the guideline released by the National Institute of Clinical Excellence (NICE) [19] aimed to identify which diagnostic and therapeutic steps are useful in managing acute upper gastrointestinal bleeding that should enable hospitals to develop a structure in which clinical teams can deliver an optimum service for people who develop this condition. They recommend offering endoscopy to unstable patients with severe acute upper gastrointestinal bleeding immediately after resuscitation and within 24 hours of admission to all other patients. They add that units seeing more than 330 cases a year should offer daily endoscopy lists. Units seeing fewer than 330 cases a year should arrange their service according to local circumstances. These recommendations are the result of a nationwide audit [20] that demonstrated that service provisions for out-of-hours endoscopy in UK was highly variable and many patients presenting with acute upper gastrointestinal bleed receive an endoscopy more than 24 hours

after presentation because endoscopy staff are typically available during the working week (9 am–5 pm) with on-call services at night and the weekend variable. For the NICE recommendation of early endoscopy to be implemented, it would involve substantial service reorganization and these costs of implementing and sustaining an earlier access to endoscopy could be significant. The Guideline Development Group, based on this information, proposed an economic model to assess the cost-effectiveness of four different endoscopy services assumed to facilitate endoscopy within different time limits after presentation of a patient with an acute upper gastrointestinal bleed: (1) weekday access to endoscopy: endoscopy staff are on-site on weekdays 8 am–5 pm; (2) everyday access to endoscopy: endoscopy staff are on-site on weekdays 8 am–5 pm and weekends 8 am–12 pm. This is assumed to allow endoscopy to occur within 24 hours of admission or start of in-patient bleed; (3) extended everyday access to endoscopy: endoscopy staffs are on-site everyday 8 am–5 pm, and are on call everyday 5 pm–12 pm. This is assumed to allow endoscopy to occur within 12 hours of admission or start of an inpatient bleed; (4) continuous access to endoscopy: endoscopy staff are on-site everyday 8 am–5 pm, and are on call everyday 5 pm–8 am. This is assumed to allow endoscopy to occur within four hours of admission or start of an inpatient bleed. Costs were associated with the health states (in hospital pre-endoscopy, in hospital post-endoscopy), transitional events (endoscopy) and with the strategy employed (staff required to implement the strategy). The base case analysis assumed 300 patients would present with acute upper gastrointestinal bleeding per year, which equates to a mean of 23 patients presenting in any 28-day period. The total costs and QALYs (Quality Adjusted Life Years) for a strategy were divided by the number of patients in the model, allowing an average cost and QALY per patient to be calculated. The strategy that provided the most QALYs was the everyday strategy, where endoscopy was assumed to occur within 24 hours. However, this came at additional cost to the weekday strategy. Using the mean costs and QALYs generated over the probabilistic sensitivity analysis, the ICER (*incremental cost-effectiveness ratio*) of the everyday strategy when compared to the weekday strategy is £36,590, which is above the NICE threshold of £20,000 per QALY. This analysis that compared four service models found results to be highly sensitive to the number of presentations a provider would expect per year. For providers expecting fewer than 330 presentations per year, the weekday strategy was most likely to be cost effective; otherwise the everyday strategy was most likely to be cost effective. This means we have to consider different operational models to achieve appropriate skilled cover.

This is the case of appropriate utilization of Gastroenterology Intensive Care Units (GICU) resources, also an important issue as all countries struggle to contain health care expenditures. The performance evaluation and review of a GICU should include its admission/discharge/triage policy. However, the activity of these GICU should not be limited to the provision of effective clinical assistance to severe gastroenterological patients. Indeed, teaching and research are also crucial goals in such intensive care units. As regards teaching, the rationale behind GICU activity is based on the concept that gastroenterology, like other medical specialties, should offer an integral assistance to its patients, from the first slightest symptoms at the ambulatory outpatient department to the most severe complication. In fact, no one is better qualified than a gastroenterologist to make clinical decisions and apply the full range of non-surgical techniques that the diagnosis and treatment of acute severe digestive diseases frequently requires. Consequently, postgraduate professional training and education of gastroenterologists, as well as internists, surgeons and nurses, is one of the fundamental aims of the GICU. This aim is achieved both directly and indirectly. In the first instance, it covers health professionals undergoing traineeships at the GICU to acquire and/or update their skills and further their knowledge. In the second case, the high standards of performance of the GICU have a pedagogical effect on the rest of the hospital. Finally, the development of research activities at the GICU is encouraged both by the rigorous protocol-based clinical care provided and by the multidisciplinary approach to case analysis and procedure assessment. In this context, clinical investigation at the GICU should be perceived not as a mere consequence of the patient care activity but rather as a goal in itself [21]. This integrated approach is aligned with the concepts of economies of scope and economies of scale which are at the heart of health care. At a simple level, economies of scope arise where it is less costly to produce two or more products (or services) in one organization than to produce each separately so that as the scope or variety of services offered increases, unit costs are reduced. Economies of scale generally are found where fixed costs of production are high in relation to variable costs such that long-run average costs fall as the scale of production increases. Such economies may exist across all lines of production or just within one

product or service area and are often attributable to technological factors or to the potential for division of labour and specialization. It is clear that it will not always be feasible to have all services thought to be desirable to support ED on a single site. The use of network arrangements is an alternative. However, these include potential increased risks to health from transferring or directing patients elsewhere, balanced against the gains from specialist treatment; the financial costs of establishing and maintaining network arrangements and clear protocols for patient pathways; and the costs of establishing and maintaining adequate training opportunities for those working within and outside of the main services to fulfil the requirements of professional standards (i.e. ensuring that staff see the required volume and mix of cases). The relative financial and non-financial costs and gains from separation need to be weighed up against the costs and gains associated with having one or more services provided in a single location. In northern Portugal, none of the institutions had sufficient resources to ensure a 24-hour gastroenterology emergency service. In October 2006, an out-of-hours endoscopy regional center was set up (Regional Gastroenterology Emergency-URGE) in one tertiary trust in Oporto covering a population of three million [22]. This is the place where 25 consultant gastroenterologists from six hospitals and eight nurses from the endoscopy unit are integrated as the emergency team, everyday from 8 pm to 8 am; they are responsible for handling gastroenterology emergencies, especially those requiring urgent endoscopy. Each institution is responsible for the remuneration for out-of-hours gastroenterology work, except for nurses that are the sole responsibility of the endoscopy unit. In this way, all are allocating human and financial resources, and future planning will be based on the information that is being recorded and audited in order to explain the additional expenditure. Patients are stabilized in the nearest hospital and transferred after agreement with the consultant gastroenterologist. The benefits of a selected transfer destination, an endoscopy nurse always scheduled and the emergency room (ER) staff prepared to receive the patient seem obvious. After the patient's arrival at the ER, they are taken care of firstly by ER staff; after the first-steps in the patient's care, the gastroenterology staff is called and the emergency GI endoscopy is performed by gastroenterology staff, while the ER staff continuously monitors the patient's condition and intervenes when needed. When appropriate and safe, the procedure takes place in the endoscopy unit or, very rarely, in theatre. After the procedures, the patients are admitted or transferred back to their institution. Although there have been several negative reports for early endoscopy, the majority recommend performing an early endoscopy in critically ill patients. URGE also adopts this approach and aggressively promotes emergency endoscopy even in the ER. The absolute benefits of an inter-hospital transfer depend on the absolute risk of death, and the relative benefit of improved survival at each transferring hospital. Many studies suggest a benefit of transfer, on average, for patients with select conditions, being the most robust data in cardiology and trauma. But the pre-hospital phase is a critical period in determining the outcome, especially for severe acute patients. There are multiple time intervals to be considered that contribute to the total pre-hospital time [23]. The activation interval is the time from the emergency call to ambulance dispatch. The response interval is the time from ambulance dispatch to the ambulance arrival at the scene. The on-scene interval is the time from ambulance arrival at the scene to the time when the ambulance departs the scene for hospital. Finally, the transport interval is the time from ambulance departure from the scene to arrival at the hospital. These four time intervals combine to give the total pre-hospital time of a patient from the emergency call to hospital door. For most patients another interval time must be considered when additional, specialized care by a consultant gastroenterologist and transfer between hospitals is required. In URGE we have patient-based data, which follows patients in and out of hospitals and across hospitals and we are working the data in what concerns appropriateness, safety, timeliness of phone calls, travel time, etc.; in other words, the full cycle of care. A similar model of care was proposed by Shokouhi et al [24] after examining the records of patients transferred for endoscopy during weekends between two general hospitals.

Organization of the emergency referral system was also the subject of a retrospective survey conducted by the regional sections of the three main Italian gastroenterological societies, AIGO, SIED and SIGE, evaluating all consecutive episodes of non-variceal upper gastrointestinal bleeding referred to sevencenters (four of which were Level-II Emergency Departments) in Rome, Italy, during a one-year period [25]. A total of 624 consecutive patients (64% males, mean age 67.6 $\pm$ 16.2 years) were included. In Italy, the Emergency Health Service is organized into Level-I Emergency Departments (ED) and Level-II ED, the latter being more complex and having greater structural and human resources. In brief,

Level-I EDs are those that do not cover all medical specialties, have fewer personnel and are usually located in smaller hospitals, while level-II EDs are located in larger hospitals, include all medical specialties and have a higher level of complexity. The authors investigated the impact of this type of organization on the management of non-variceal upper gastrointestinal bleeding and underlined that an emergency health system intended to offer multistep medical assistance according to patient severity would not be efficient if admission to hospital care is indiscriminate, and therefore not based on patient needs, but mainly influenced by geographical vicinity. They conclude that 30-day in-hospital mortality rate was lower when patients were admitted to EDs with greater resources (nearly two-thirds reduction). More seriously ill patients were less frequently referred to hospitals with the better organized Level-II EDs. So, strategies to improve the referral of patients in relation to the severity of their clinical status are therefore needed in the Lazio region, although the cost-effectiveness ratio of this policy remains to be evaluated in order to justify the supplemental economic resources allocated to Level-II EDs as a function of increased survival.

Practice Points

- For each emergency gastroenterological condition, definition of the level of health care that must be provided is essential.
- There is an urgent need to incorporate the gastrointestinal emergencies, namely gastrointestinal bleeding, into the overall emergency response as was done for heart attack and stroke.
- Evaluate geographic access to health services determining the patient travel time to a specified facility.
- Identify measurable performance indicators with information systems to monitor, analyse, and trend data. Ultimately, we want an emergency care delivered that is timely, consistent, appropriate, cost-effective and, most importantly, beneficial to patient outcomes.

A growing body of literature and reports from innovative practices and care systems from other specialties are beginning to clarify the elements associated with more effective care coordination and more successful referrals and transitions and these experiences can and should be extrapolated to emergency gastroenterology. We realize that emergency endoscopy services need to be better organized; that gastroenterologists can no longer be drowned in general internal medicine in the ED but add their technical expertise in high-risk situations or, conversely, adding fluidity and discharge patients earlier. Despite the quantity of proposals (transfer the patient or call or transfer the gastroenterologist), there remains a distinct lack of reference to all service provision (structure + process + outcome) and models of care, which must be the driving force for organizing, evaluating and facilitating medical care across the full care cycle. In the light of these findings, and the general lack of a model of care for acute gastrointestinal service delivery, there is clearly a pressing need for more research and planning of how services should be delivered and the resources required to meet the patient and professional needs. Finally we conclude that gastrointestinal emergencies, especially gastrointestinal bleeding, have not been incorporated into the overall emergency response, despite extensive debate on the fact that it is a time-critical procedure as set out in the recently published CROMES report [26].

Research Agenda

- Research on the development of strategies and emergency models of care in gastroenterology is needed, not just on clinically-focused problems but also on logistical and managerial ones.
- This research should be coordinated, tied to real practice, and focused on both outcomes and processes across all six domains of health care quality.
- Research on appropriate care can only be understood over the full cycle of care (complete process of care); patient-based data, which follow patients in and out of hospitals and across hospitals, is the only robust quality and safety indicator and should be the focus of research.

Summary

The patient needs and expectations, the increased specialization, the availability of new treatments and technologies, the constant pressure from rising demand and limited resources and the challenging financial environment, mean that maintaining the 'status quo' may not be a safe option. So, there is an acute need to close the gap in gastrointestinal emergencies delivery, between what is known and what is actually available in most settings.

It is essential that gastroenterology is a 24-hours-a-day, 7-days-a-week specialty, and consequently the service should be organized around the patient's needs. New models of care should be beneficial to patients and staff, rather than just being considered for purely economic or administrative reasons. But, unlike other clinical areas, cardiac or stroke care, the field of emergency care in gastrointestinal emergencies, currently lacks a uniform set of metrics which informs providers, administrators, and consumers about the status of their care. All of this calls for a coordinated approach and organizational (national, regional or local) models of care. These must become the driving force for organizing, evaluating, and facilitating medical care across the full care cycle. We found no studies directly addressing the causal relationship between all three variables of care: structure, processes and outcomes, although in some, associations between outcomes and resources could be inferred. This review suggests that more research is needed to establish a robust and cost-effective model of gastroenterology emergency service delivery.

Conflict of interest statement

There is no conflict of interest declared by the authors.

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II. BACKGROUND

IIa. Quality in Health Care

IIa1. Definition and Dimensions of Quality

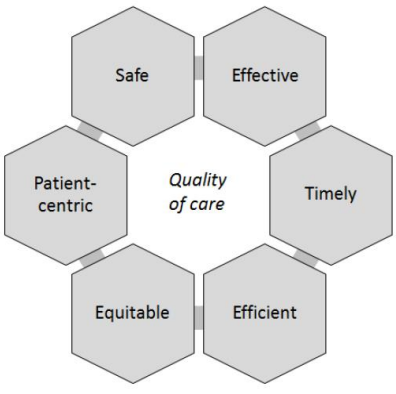
Over time, quality has been defined in several ways. Within healthcare, there is no universally accepted definition of quality. Quality of care encompasses many definitions, dependent on the author or institute defining the term, or if they are used in relation to health care or health care systems. For instance, the Portuguese National Health Service represents a universal care system run by the government's Department of Health in a structured and uniform manner. But, but for example, The United States' health care system, is operated by several different entities, including the government, managed care organizations, and insurance companies. Donabedian, the leading figure in the theory and management of quality of care, had already suggested that quality will always differ from person to person, largely dependent on “where we are located in the system of care and on what the nature and extent of our responsibilities are” (Donabedian 1988).
Every healthcare organization provides a different level of quality, with higher levels of quality always correlating with the experience of those providing the care (HS 1990). High quality standards do rely heavily on a well-organized system, with real improvement in quality dependent on continuous improvement throughout the organization, through constant effort to reduce waste, rework, and complexity (Berwick 1989). The more efficient and content the work environment is, the higher the quality of care experienced by the patient.

At the present, I believe that for most of our health care professionals, the definitions of quality rely just on the technical excellence with which care is provided and the characteristics of interactions between provider and patient, as stated by Blumenthal (Blumenthal 1996).

In 1980, Donabedian defined care of high quality as “that kind of care which is expected to maximize and inclusive measure the patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts" (Donabedian 1980). In 1984, the American Medical Association defined high-quality care as care “which consistently contributes to the improvement or maintenance of quality and/or duration of life"(1986). The association identified specific attributes of care that

should be examined in determining its quality, including an emphasis on health promotion and disease prevention, timeliness, the informed participation of patients, attention to the scientific basis of medicine, and the efficient use of resources. One of the most cited definitions, was formulated by the Institute of Medicine (IOM) in 1990, and defined quality as the “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Lohr KN 1992). And in fact, the US health care system has been at the forefront of health care QI efforts for over a century. Dr. Ernest Amory Codman (1869–1940), a physician at the Massachusetts General Hospital in Boston, was among the first in the developed world to highlight the problem of poor quality in health care. He subsequently set a standard for open, honest, and public evaluation of the end results of medical and hospital care (Neuhauser 1990). Since then, much work has been done in the USA by governmental agencies such as the Joint Commission on Accreditation of Healthcare Organizations and the Agency for Healthcare Quality and Research, and various professional societies. However, fourteen years ago, two reports from the IOM suggested that there was a long way to go before Americans could enjoy safe and clinically effective service (Institute of Medicine 1999; Medicine 2001). The first report, *To Err is Human* estimated that nearly 44,000 Americans died each year as a result of medical errors. More people died in a given year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. Total national costs of preventable adverse events were estimated to be between $ 17 billion and $29 billion. The second IOM report *Crossing the Quality Chasm*, asked for a fundamental change, recommending that the delivery of health care in the 21st century should be based on 6 key dimensions: 1) safety—avoid injury to patients from the care that is intended to help them; 2) timeliness—reduce waits and harmful delays; 3) effectiveness—provide services based on scientific knowledge to all who could benefit and refrain from providing services to those not likely to benefit [avoiding overuse and underuse, respectively]; 4) efficiency—avoid waste; 5) equitability—provide care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographical location, and socioeconomic status; 6) patient centeredness—provide care that is respectful of and responsive to individual patient preferences, needs, and values. Other countries have faced similar challenges. The Britain's National Health Service (NHS), as constituted in 1948, was a

Figure 2: The quality dimensions proposed by the Institute of Medicine



universal system, funded predominantly by taxation, that made health care available to the whole population and had a strong focus on health care QI, especially since the early 1990s. At that time, emphasis was placed on improving standards of care, and all professionals were mandated to scrutinize their practices through clinical audit. Clinical audit required professionals to look systematically at the procedures used for diagnosis, care, and treatment; to examine how associated resources were being used; and to investigate the effect care had on the outcome and quality of life for the patient. Various national and regional initiatives were launched to support these efforts and many organizations involved.

I think that one of the best definitions of quality belongs to Harteloh (Harteloh 2003): “Quality is an optimal balance between possibilities realized and a framework of norms and values.” This conceptual definition reflects the fact that quality is an abstraction and does not exist as a discrete entity. Rather it is constructed based on an interaction among relevant actors who agree about standards (the norms and values) and components (the possibilities). This is in accordance with Davila's abstract definition "For many, quality health care is like beauty or pornography—they know it when they see it but they just can’t define it" and " Ultimately, the answer to the question “Should it be done?” rather than “Can it be done?” will determine what quality health care is and is not" (Davila 2002; Davila 2002)).

The Portuguese National Health Plan for 2012-2016 defines quality in health as "... the provision of affordable and equitable healthcare, with an excellent professional level, taking into account the available resources, while achieving the citizen's adhesion and satisfaction. It also implies the adequacy of healthcare to the needs and expectations of citizens and the best possible performance".

In summary, there are many different definitions of quality in health care. The characteristics emphasized vary according to the perspectives of the people and the organizations offering them. What is common to all definitions is the need to see quality of care as much more than just a matter of technical skills and the supply of services. Good quality of care must also respect the perspectives and needs of the patient and meet standards in ways that are safe, effective, patient-centered, timely, efficient and equitable.

Regardless of what definition of quality of health care is used, it must be kept in mind that every system, every process and every patient are different. Those who work in health care need to find ways to make QI an integral component of everyone’s work. This means

investments in people, technology, and processes. Most importantly, it means the support of our leaders and their commitment. In spite of this difficulty in defining the concept, there has always been the need to measure and improve quality in health care.

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II. BACKGROUND

IIa2. Quality Assessment and Improvement

IIa2.1. The History of Quality Improvement

There is no single definition of QI, and no approach appears to be more successful than another. However, there are a number of definitions that describe QI as a systematic approach that uses specific techniques to improve quality. The most important ingredient in successful and sustained improvement is the way in which the change is introduced and implemented. The key elements are the combination of a change (improvement) with a method (an approach or specific tools) to achieve a better outcome.

Understanding the basics of quality is important to our ability to improve it. Thus, this section briefly examines the main concerns that led to the pursuit of quality in industry.

During the early days of manufacturing, an operative's work was inspected and a decision made whether to accept or reject it. As businesses became larger, so did this role, and full time inspection jobs were created. Later on, these changes led to the birth of the separate inspection department with a "chief inspector", reporting to either the person in charge of manufacturing or the works manager. With the creation of this new department, there came new services and issues, standards, training, recording of data and the accuracy of measuring equipment; the need to address defect prevention emerged. Hence the quality control department evolved, in charge of which was a "quality control manager", with responsibility for the inspection services and quality control engineering.

The beginning of the 20th century marked the inclusion of "processes" in quality practices. A "process" is defined as a group of activities that takes an input, adds value to it and provides an output, such as when a chef transforms a pile of ingredients into a meal. Walter Shewhart, a statistician, began to focus on controlling processes in the mid–1920s, making quality relevant not only for the finished product but for the processes that created it. Shewhart recognized that industrial processes yield data and that this data could be analyzed using statistical techniques to see whether a process is stable and in control, or if it is being affected by special causes that should be fixed. They differ from product orientation in that they make quality relevant, not only for the finished product, but also, for the process that created it. At that time, Japan's industrial system was virtually destroyed,

and it had a reputation for cheap imitation products. The Japanese recognized these problems and set about solving them with the help of some notable quality gurus like, Juran, Deming and Feigenbaum. In the early 1950's, quality management practices developed rapidly in Japan, and become a major theme in Japanese management philosophy, such that, by 1960, quality control and management had become a national issue. By the late 1960's/early 1970's Japan's imports into the USA and Europe increased significantly, due to its cheaper, higher quality products, compared to the Western counterparts.

In 1969 the first international conference on quality control, sponsored by Japan, America and Europe, was held in Tokyo. In a paper given by Feigenbaum, the term "total quality" was used for the first time, and referred to wider issues such as planning, organization and management responsibility. Ishikawa gave a paper explaining how "total quality control" in Japan was different, it meaning "company wide quality control", and describing how all employees, from top management to the workers, must study and participate in quality control. The quality revolution in the West was slow to follow, and did not begin until the early 1980's, when companies introduced their own quality programs and initiatives to counter the Japanese success (UK Governement 2005; ASQ 2011).

A guru, by definition, is a good person, a wise person and a teacher. A quality guru should be all of these, plus have a concept and approach to quality within business that has made a major and lasting impact. Some examples of quality gurus are (table 1):

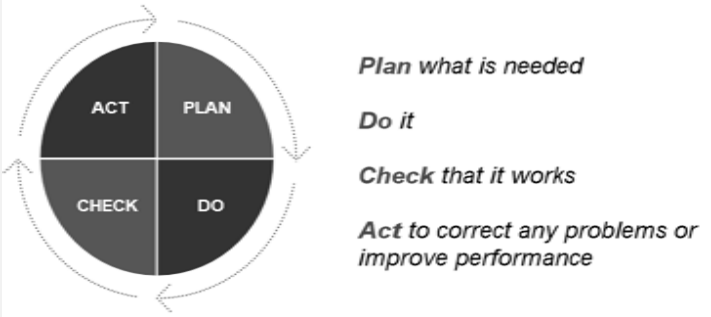
Table 1: The gurus and their approach to quality improvement.

Leader	Approach
W Edwards Deming	Plan, Do, Check, Act (PDCA) cycle
Joseph M Juran	Quality Trilogy
Armand V Feigenbaum	Total Quality Control
Kaoru Ishikawa	Seven basic Tools of Quality Techniques such as his cause and effect "fishbone" tool.

W Edwards Deming placed great importance and responsibility on management, at both the individual and company level, believing management to be responsible for 94% of quality problems. He introduced a new complete philosophy of management, statistical evidence that quality is built and the responsibility is to change from numbers to quality.

Deming also encouraged a systematic approach to problem solving and promoted the widely known Plan, Do, Check, Act (PDCA) cycle (figure 3). The PDCA cycle is also known as the Deming cycle, although it was developed by a colleague of Deming, Dr Shewhart. The cycle is about learning and ongoing improvement, learning what works and what does not in a systematic way; and the cycle repeats; after one cycle is complete, another is started.

Figure 3: The Deming cycle: Plan, Do, Check, Act, a systematic approach to problem solving.



Adapted from the Department of Trade and Industry

Joseph M Juran developed the quality trilogy – quality planning, quality control and QI. Good quality management requires quality actions to be planned out, improved and controlled. Juran emphasized the necessity for ongoing QI through a succession of small improvement projects carried out throughout the organization. His ten steps to QI are: build awareness of the need and opportunity for improvement; set goals for improvement; organize to reach the goals; provide training; carry out projects to solve problems; report progress; give recognition; communicate results; keep score of improvements achieved and maintain. Each person along the chain, from product designer to final user, is a supplier and a customer. In addition, the person will be a process, carrying out some transformation or activity.

Armand V Feigenbaum was the originator of “total quality control”, often referred to as total quality and defined as “an effective system for integrating quality development, quality maintenance and QI efforts of the various groups within an organization, so as to enable production and service at the most economical levels that allow full customer satisfaction”. He proposed three steps to quality: quality leadership; modern quality technology and organizational commitment.

Kaoru Ishikawa made many contributions to quality, the most noteworthy being his emphasis on the human side of quality, the Ishikawa diagram and the assembly and use of the “seven basic tools of quality”, as detailed in table 2:

Table 2: The seven basic tools of quality

Pareto analysis	which are the big problems?
Cause and effect diagrams	what causes the problems?
Stratification	how is the data made up?
Check sheets	how often it occurs or is done?
Histograms	what do overall variations look like?
Scatter charts	what are the relationships between factors?
Process control charts	which variations to control and how?

All these Gurus' concepts can apply to healthcare. The healthcare system itself is unbelievably complicated and costs have raised increasingly. Patients are demanding more and better care. Errors are widespread. Our population is aging. At times, the problems seem unsolvable.

The pursuit of healthcare quality came out of a concern for better health or lost lives as perceived by individual professionals, as Florence Nightingale. Florence Nightingale was a pioneer developer of survey instruments and in the graphical presentation of data. At a time when research reports were only beginning to include tables, Nightingale was using bar and pie charts, which were color coded to highlight key points [as high mortality rates under certain conditions] (Nightingale 1988). In recent years however, it is evident that the primary concern for quality comes from a pressing need to satisfy the customer (or patient) both in industry and healthcare. This has become the prerequisite for staying in business and most of the experts (Deming, Juran, Feigenbaum) in the field of quality have argued that focusing on quality is more beneficial than focusing on profit and consider top management involvement as vital.

Quality now, represents a system of methodologies and practices, common to healthcare and industry, and an ongoing commitment to excellence that encompasses all issues and engages all individuals within an organization.

Although the concept of quality management and its control in healthcare is not as advanced as it is in industry, this may be explained by the difference in the fundamental

concern for quality and the nature of industrial and healthcare processes. On the other hand, quality approaches observed in health care have been in a more reactive form.

IIa2.2. Assessing and Measuring Quality in Healthcare

In 1996, the NEJM, started to publish a series of short series on the quality of medical care. The purpose of these series was to review the major technical concepts and issues that were pertinent to current discussions about the quality of care, to place those discussions in a political and social context, and to provide some guidance on how changes in techniques for measuring and improving quality could affect doctors and patients over the next decade (Blumenthal and Epstein 1992; Blumenthal 1996; Blumenthal 1996; Blumenthal and Epstein 1996).

Since 1997, the emphasis on quality has increased (Health 1998). The concept of clinical governance has been introduced, and all NHS organizations were required to ensure robust arrangements for it. Unlike clinical audit, which was a professional-only activity, clinical governance requires professionals to work with managers. Clinical governance is "a framework through which NHS organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." But there were still reasons to keep worried about health care quality, as summarized briefly by Rajan Madhok in 2002 (Madhok 2002). Although it is worth noting that the subject is quite complex, his analysis identified a number of contributory causes. First, the NHS was overloaded with policy matters and constant outpouring of national guidance. There was an unprecedented amount of policy material in the NHS relating not just to QI but also to other aspects of the service. Second, alongside the policy avalanche, there have been structural adjustments. These structural changes raised uncertainty and anxiety, leading to staff turnover and loss of continuity of work. Specific to the quality agenda were a number of national organizations with overlapping missions and hence confused responsibilities. Third, although there was acceptance of a commitment to creating a supportive and no punitive environment, some doctors and their leaders were afraid of a blame culture. Fourth, integrating QI efforts into mainstream work was difficult, because of the lack of robust information systems. Fifth, QI efforts were being led by experts and the practitioner left apart. Sixth, QI is a long-term program and the sense of urgency demonstrated by the media and the government has influenced the way in which events have turned out. Seventh, current arrangements for QI were not patient-centered. QI arrangements were organization specific and as such merely pass the responsibility from

one organization to another, compromising the patient's journey. He concluded that change management in the NHS was not well understood and practiced. From this we realize that all the issues mentioned are of key importance for the implementation of any QI initiative. But, what emerges from these lessons is that it is difficult to move from theory to practice, without a strong commitment to organizational culture along with the engagement and empowerment of all professionals.

Managing organizational culture is increasingly viewed as an essential part of health system reform based on the premise that a major cultural transformation of the organization must be secured alongside structural and procedural change to deliver desired improvements in quality and performance. In fact, the culture of an organization is a key consideration in the design and implementation of QI initiatives. For example, health care cultures that emphasize group affiliation, teamwork, and coordination have been associated with greater implementation of continuous QI practices and higher functional health status in coronary artery bypass graft patients (Shortell, O'Brien et al. 1995; Shortell, Jones et al. 2000). By contrast, organizational cultures that emphasize formal structures, regulations and reporting relationships, appear to be negatively associated with QI activity (Ferlie and Shortell 2001).

An essential feature of organizational culture in health care institutions will be one that creates accountability for QI at all levels, from top-level management to individual caregivers. Another important element will be optimizing communication and social networking in an effort to break down hierarchies and divisions that limit information sharing. Clinical care is ultimately delivered to patients along relatively autonomous service lines (i.e. gastroenterology services, surgery services, oncology services), and strategies need to be developed to achieve synergy among them. In other words, a corporate culture which can be defined as 'the deeper level of basic values, assumptions and beliefs, that are shared by members of an organization (Johnson G 1984). Culture has a powerful effect on an organization and is recognized by many as the 'glue' that holds an organization together and allows it to adapt to changing environments.

In 2006, The World Health Organization (WHO), following this pattern of organizational commitment, published "Quality of care: a process for making strategic choices in health systems" and suggested that a health system should seek to make improvements in six areas or dimensions of quality, which are named and described below. These dimensions require that health care should be:

- Effective: delivering health care that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need;
- Efficient: delivering health care in a manner which maximizes resource use and avoids waste;
- Accessible: delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;
- Acceptable/patient-centered: delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities;
- Equitable: delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status;
- Safe: delivering health care which minimizes risks and harm to service users.

One important concern of this document was to support the role of policy and strategy development and to be able to differentiate quality roles and responsibilities in the various parts of a system. They identified six domains which are interrelated and intended to help policy-makers to address quality issues at a more strategic level. They emphasized that the challenge to health systems is to ensure that engagement with patients and the population is at the heart of all policies and strategies for QI.

In a period of economic constraints and healthcare reforms, people demand greater quality in the health care they receive and accountability in the health care system. Evidence for the need to improve quality is widespread. Although difficult to quantify with accuracy, there is clear evidence that gaps exist between what is known to be effective and is, from the best available evidence and research, and what happens in practice.

Multiple reports indicate that variation in clinical practice is common even where agreed clinical practice guidelines exist. Wide, unwarranted variations that cannot be explained by illness severity or patient factors are frequent (Davis and Taylor-Vaisey 1997; Wennberg 2002; Buchan 2004; Buchan, Sewell et al. 2004; Grol and Buchan 2006; Evensen, Sanson-Fisher et al. 2010). Studies report high rates of inappropriate care and error during care-giving (Institute of Medicine 1999; Medicine 2001). And variability may be particular relevant in the emergency setting; the work of specialists is extremely varied because it is based not only on the available resources that can be supplied but also on the nature of unpredictable demand. The structure and organization of the department, the technology and the professional's level of uncertainty go head to head with a series of

variables (morbidity, socioeconomic conditions and level of education, age, sex) during a process that lasts for a short amount of time and that requires urgent attention.

Different perspectives on quality will logically call for different approaches in its measurement and management. Thus, a special attention must be paid to how to improve the quality of care to everyone, in our everyday practice. Unfortunately, the current QI literature predominately focuses on case reports that describe projects in a single setting and do not provide the in-depth project evaluation necessary to fully understand QI in health care. Even systematic reviews of QI have a hard time reaching definitive conclusions as they generally conclude project evaluations and cannot establish whether improvements in quality occur, if improvements were present and whether those improvements were even causally related to the QI effort (Vest and Gamm 2009; Dellifraine, Langabeer et al. 2010). Also, the literature has identified: a lack of documentation about how major illnesses are treated in most health care systems; a lack of systematic outcome assessment; a lack of resource evaluation related to quality for specific diseases; persisting variations among providers in care for similar patients; for most diseases, potential quality problems and their prevalence and incidence are unknown in many countries (Chassin and Galvin 1998; Schuster, McGlynn et al. 1998).

In the health care field, measuring quality of care has traditionally relied on the structure-process-outcome framework developed by Donabedian (Donabedian 1988). Avedis Donabedian identified the three dimensions that can be utilized to assess quality of care (structure, process, and outcome) that would later become the core divisions of the Donabedian Model. “Evaluating the Quality of Medical Care” became one of the most frequently cited public health-related articles of the 20th century (Donabedian 2005). Donabedian defines structure, process, and outcome, and clarifies that these categories should not be mistaken for attributes of quality, but rather they are the classifications for the types of information that can be obtained in order to infer whether the quality of care is poor, fair, or good. Furthermore, he states that in order to make inferences about quality, there needs to be an established relationship between the three categories and that this relationship between categories is a probability rather than a certainty. Structure in health care delivery can refer to the physical plant or the organizational structure. Processes are specific patient interventions performed by health care professionals and resulting in an outcome. Some examples of processes are, use and timeframe of emergency endoscopy in acute upper bleeding and patient length of stay in the emergency department. Outcomes are the result of the patient's interaction with the delivery health care system. Examples of clinical outcome measures include mortality or length of stay, readmission

rates, morbidity measures such rebleeding after therapeutic endoscopy. Present measurement systems may focus on any one of the components. Clinical performance measurements, which include process and outcome measures, are in demand in health care today.

Also indicators provide a quantitative basis for clinicians and organizations aiming to achieve improvement in care and the processes by which patient care is provided. Indicator measurement and monitoring serves many purposes. They make it possible to: document the quality of care; make comparisons (benchmarking) over time between places (e.g. hospitals); set priorities (e.g. organizing medical care); support QI. The use of indicators enables professionals and organizations to monitor and evaluate what happens to patients as a consequence of how well professionals and organizational systems function to provide for the needs of patients.

Indicators allow the quality of care and services to be measured. This assessment can be done by creating quality indicators that describe the performance that should occur for a particular type of patient or the related health outcomes, and then evaluating whether patients' care is consistent with the indicators based on evidence-based standards of care.

Clinical indicators (CIs) are a form of performance measurement, a method for assessing the quality of care by examining the incidence of specific events or incidents. Although similar performance measures have been utilized in health care since the 1980s, the call for CIs intensified after the concerns around patient safety (Thomson and Lally 1998). Clinical indicators can be part of, or linked to, broader health, quality, safety or performance indicators. The difference between CIs and broader indicators is that CIs are said to be more suitable for internal QI, while performance indicators are appropriate for external appraisals (Wollersheim H 2007). Data on clinical indicators have been developed, and the results compared, at international, national, regional, health systems, health services and individual clinician levels. Healthcare institutions may use CIs at any or all of these levels at any given time (Mattke, Epstein et al. 2006; McLoughlin, Millar et al. 2006).

We find many definitions of CIs in the literature (table 3). According to Mainz, the use of indicators enables professionals and organizations to monitor and evaluate what happens

to patients as a consequence of how well professionals and organizational systems work. Indicators are, however, not a direct measure of quality (Mainz 2003).

Table 3: Definitions of clinical indicators

Mainz's definition (Mainz 2003)	The United Kingdom's National Health Service definition (Collopy 2000)	Australian Council on Healthcare Standards' definition (Rockville 2009)
"... the measure the extent to which set targets are achieved. They are expressed as numbers, rates, or averages that can provide a basis for clinicians, organizations, and planners aiming to achieve improvement in care and the processes by which patient care is provided. They can be measures of structure, process, and outcome, either as generic measures relevant for all diseases, or disease-specific measures that describe the quality of patient care related to a specific diagnosis."	"… succinct measures that aim to describe as much about a system as possible in as few points as possible. Indicators help us understand a system, compare it and improve it." 18 At a similar level, clinical indicators have been described as "… a measure of the clinical management and/or outcome of care".	"... simply a measure of the clinical management and/or outcome of care. A well-designed indicator should 'screen', 'flag' or 'draw attention' to a specific clinical issue. Usually rate based, indicators identify the rate of occurrence of an event. Indicators do not provide definitive answers; rather they are designed to indicate potential problems that might need addressing, usually demonstrated by statistical outliers or variations within data results. They are used to assess, compare and determine the potential to improve care. Indicators are therefore, tools to assist in assessing whether or not a standard in patient care is being met."

Indicators should be based on the best available evidence. Sackett et al. describe this as 'the integration of best research evidence with clinical expertise and patient values'. The strength of evidence for an indicator will determine its scientific soundness or the likelihood that improvement in the indicator will produce consistent and credible improvements in the quality of care (Sackett DL 2000). Namely, CIs measure the extent to which set targets are achieved. They are expressed as numbers, rates, or averages that

can provide a basis for clinicians, organizations, and planners aiming to achieve improvement in care and the processes by which patient care is provided. An initial step towards good measurement practice begins by realizing that indicators can be classified in many different ways and by identifying types of indicators that reflect the aspects of health care delivery we wish to measure. Ideally these concepts should be capable of capturing the Donabedian Model (Donabedian 2005). They can be measures of structure (the tools, resources, and organizational components), processes (activities that connect patients, physicians, and staff), and outcomes (results), either as generic measures relevant for all diseases, or disease-specific measures that describe the quality of patient care related to a specific diagnosis. CIs can be categorized according to its purpose: rate-base or sentinel; related to structure, process or outcome; generic or disease specific; type of care (preventive, acute or chronic); screening, diagnosis, treatment and follow-up. The six aims of improvement, identified by the IOM, can also be used to categorize CIs (Medicine 2001), as well as those from the WHO, described above. The decision as to which indicator is selected depends on the question we are trying to answer. For each concept, there are several different indicators that can be tracked, as exemplified in table 4.

Table 4: Example of CIs concept

Concept	Potential Indicators for this process
Care of emergency acute upper bleeding patients	• The total number of patients • The ED transfer rate • The percentage of ED patients admitted as inpatients • The patient wait time to endoscopy procedure

After selecting a specific indicator, we create an operational definition. The next step is to develop a data collection plan; there are several important data collection issues that require some elaboration, most notably stratification and sampling. Stratification is the separation and classification of data according to selected identifiers. The objective of stratification is to create categories within the data to discover patterns that would not otherwise be observed if the data were aggregated together (e.g. day of the week; time of the day; time of the year; severity of the patient; referral vs. non-referral). So, if we want to organize our indicator development form we must be able to answer some questions: 1)

What process or outcome does this indicator measure?; 2) Why do I want to measure this indicator?; 3) Which objective does it satisfy?; 4) Which dimension of quality does it cover?; 5) Are there literature references for this indicator?.

A frequently asked question is whether structure, process or outcome is the best measure of quality of care. Evaluations of quality that rely only on structural elements implicitly assume that well-qualified people working in well- organized settings will provide high-quality care. Good outcomes can result even when the care is clearly deficient. The reverse is also possible: although the care is excellent, the outcome may not be a good one. Ultimately what a particular outcome tell us about quality of care depends crucially on whether the outcome can be attributed to the care provided. In other words, we have to examine the link between the outcome and the antecedent process and determine whether the care provided was appropriate and whether it was provided skillfully. Once it has been established that certain procedures used in specific situations or for certain patients are clearly associated with good results, the presence or absence of these procedures for such patients or situations can be accepted as evidence of good or bad quality. Such evidence-based structural or process indicators may be referred to as 'outcome validated' and represent direct measures of quality.

Process indicators are especially useful when: QI is the goal of the measurement process; an explanation is sought for why specific providers achieve particular outcomes; short time frames are necessary; performance of low volume providers is of interest; and when tools to adjust or stratify for patient factors are lacking. Comparisons of process data are easier to interpret and more sensitive to small differences than comparisons of outcomes data. A process indicator can measure whether or not an upper bleeding patient receives the right medication, whereas 30-day mortality rates may be difficult to interpret (Palmer 1998; Mainz 2003).

Palmer suggests that outcomes data are useful if : outcomes can be measured that are affected by health care; long time-frames are possible; performance of whole systems should be studied; or if a high volume of cases is available. Outcomes data are most useful for tracking care given by high-volume providers over long periods of time, and for detecting problems in implementation of processes of care (Palmer 1998) A reasonable strategy is to select measures that meet the needs of each particular condition or treatment; sometimes these will be structure or process measures, and sometimes outcomes measures. More often, they will be a combination of the two (Mainz 2003).

In practice, to assess quality, using structure, process or outcome measures, we need to know what constitutes good structure, good process, or good outcomes. We need criteria and standards for those aspects of care. Criteria refer to specific attributes that are the basis for assessing quality. Standards express quantitatively what level the attributes must reach, to satisfy the expectations about quality.

Quality measurement and improvement in endoscopy are essential for the quality of care in gastroenterology. Publications have primarily addressed issues of technical quality and patient safety (Baron, Petersen et al. 2006; Cohen, Safdi et al. 2006; Faigel, Pike et al. 2006; Jacobson, Chak et al. 2006; Rex, Petrini et al. 2006; Axon 2009; Coe, Raimondo et al. 2009; Colton and Curran 2009; Crispin, Birkner et al. 2009; Faigel and Cotton 2009; Ho and Wiersema 2009; Lieberman, Faigel et al. 2009; Polkowski, Gerke et al. 2009; Rembacken 2009; Siddiqui, Yang et al. 2009; Al-Haddad, Gill et al. 2010). The first guidelines or position statements on various aspects of quality and safety indicators have been developed by the British Society of Gastroenterology, the American Society for Gastrointestinal Endoscopy and the American College of Gastroenterology, the World Organization of Digestive Endoscopy, the International Agency for Research in Cancer and the Canadian Association of Gastroenterology. These guidelines are all procedure based. They don´t address patients needs and don't provide a framework for adoption in the overall context of endoscopic services. For example, in the British guidelines, quality and safety have been separated to highlight the difference between the benefits (quality) and harm (safety) of endoscopic procedures. The indicators have been separated further into two broad categories: relatively fixed items: structure, process and staffing and more dynamic indicators: auditable outcomes and quality standards. However, recognition of the need for great patient focus in health care has led to include other dimensions of quality: patient access to procedures; the appropriateness and timeliness of procedures, and patient's comfort and satisfaction. The most recent guidelines, like the Canadian ones, are patient-centered and try to cover the patients' journey (Armstrong, Barkun et al. 2012).

A comprehensive quality assurance program should incorporate quality across all aspects of endoscopy. One good example is the Global Rating Scale (GRS) which has been implemented in endoscopy departments throughout England and validated in Netherlands (Sint Nicolaas, de Jonge et al. 2012). The development of the GRS was prompted by the introduction of a colorectal cancer screening programme and by shortcomings in the quality of endoscopy (Bowles, Leicester et al. 2004; Radaelli, Meucci et al. 2008).

A national roundtable on health care quality, established in 1995 by the IOM stated that a comprehensive approach to measuring the quality of care requires attention to three different kinds of quality problems: too much care [overuse], too little care [underuse], and misuse [flaws and errors in technical and interpersonal aspects of care] (Medicine 1999):

a) Too Much Care: unnecessary or inappropriate care: an example of overuse include the excessive or unnecessary use of emergency endoscopy procedures; this practice may result in still further procedures (laboratory) and activities (patient transfer) in a cascade of interventions that might have been avoided and that might make patients vulnerable to harmful side effects with wasting of money and resources, that could be put to more effective use.

b) Too Little Care: underuse of needed, effective, and appropriate care: many studies have demonstrated the large gap between what is known to be effective care and what patients actually receive, as mentioned before about variability in clinical practice.

c) Misuse: shortcomings in technical and interpersonal aspects of care: inferior care results when the performance of health care professionals or support systems is inadequate. Examples include preventable endoscopic complications or failure to monitor or follow up those complications.

In 2011, Katharine A. Germansky and Daniel A. Leffler, realizing that only endoscopy has been the focus of QI work, reviewed a variety of areas in clinical gastroenterology where, existing guidelines and published data suggest both, the need and viability of active quality assurance measures (Germansky and Leffler 2011). The authors suggested that as mortality rates for gastrointestinal bleeding remained stubbornly high, mortality rates should be monitored and case fatalities reviewed, ideally by a multidisciplinary team, in order to identify areas for improvement. Indeed, the authors referred to clinical audit. Clinical audit is a cyclical process, where standards are agreed and data collected. Findings from the analysis of collected data show whether or not standards are being met. If they are not being met, changes are planned and implemented, and data are collected for a second time and analyzed to see if any improvements have resulted from these changes. The definition of clinical audit, endorsed by the National Institute for Clinical Excellence is: clinical audit is a QI process that seeks to improve patient care and outcomes through a systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery (NICE 2002). This means, the systematic approach encouraged by Deming.

Gastrointestinal endoscopy is a complex diagnostic and therapeutic activity that demands a high level of skill and knowledge on the part of the operator. However, high-quality endoscopy requires more than a skilled operator. The delivery of high-quality endoscopy services, in a cost-effective manner consistent with the broader needs of a health care system, requires a formal QI framework that addresses all aspects of endoscopy service delivery: from the patient's initial contact with a health care provider through to documentation of outcomes. Recognition of the patient as the focus of the endoscopy process provides a structure for integrating the efforts needed to ensure a high-quality service.

So, measurement of health care quality serves a range of objectives, including the following: providing data to inform QI efforts; to know if a facility meets previously established standards; identifying and possibly eliminating substandard performance; monitoring and reporting information about changes in quality of care over time; and addressing the health needs. In general, either processes or outcomes may be valid measures of quality. For an outcome to be a valid measure of quality, it must be closely related to processes of care that can be manipulated to affect the outcome. Likewise, for a process to be a valid measure of quality, it must be closely related to an outcome. Each one plays a part in quality measurement. Structural measures of quality typically include the characteristics of the resources in the health care system, including individual practitioners, groups of practitioners, organizations and systems of care, geographic location, and accessibility of services. They are measures of the presumed capacity of the practitioner or provider to deliver quality health care. Peter Cotton drew attention to this problem some years ago, in the endoscopy setting (Cotton 2011). Endoscopists cannot work without good facilities, equipment, and a team of well-trained and motivated staff; so, one point that must attract our attention relates to the metrics of quality in endoscopy units. Measures of performance may include interpersonal aspects of care, service, timeliness, and convenience. Technical aspects of care include the timeliness and accuracy of diagnosis, the appropriateness of therapy, complications, and mishaps during treatment, and coordination of care across delivery settings. Errors in carrying out the complex series of steps often involved in patient care may contribute to preventable deaths or failures. Health outcomes include the traditional measures of survival (expressed as risk-adjusted mortality), unintended effects of treatment (e.g., perforation), and the relief of symptoms. Such measures may be specific to a given health problem and may focus on other outcomes (e.g., thirty-day survival, complications from disease, or free of bleeding after successful therapeutic endoscopy). An outcome measurement is in

some ways the ultimate form of quality measurement because, what interests most people is whether care has improved the patient's health. Nevertheless, the pitfalls are great; to be useful for QI, outcomes data need to provide information with a high level of clinical detail and be provided in a sufficiently clear manner that providers can know what processes must be changed.

Many, in the health care system have begun to apply a model of QI called continuous QI or total quality management. One assumption of this model is that the health care organizations and systems within which professionals practice can always improve. One way to acquire this improvement is to set up continuous monitoring systems that alert the organization when performance in some area is slipping or to confirm that efforts at improving care are succeeding, or both.

Assessing the effectiveness of health care, clearly requires the measurement of health improvement—the difference in health with and without some intervention. Most countries, like Portugal, face high demands on their health care systems and a limited budget to meet these demands. Clinicians often face situations where there is information demonstrating the benefits from an intervention or treatment, but, there is still little context in which to understand how much their patients will value these benefits and whether the benefits are significant enough to merit expending scarce resources. Furthermore, it could be argued that it is an ethical responsibility to consider these issues as the savings on spending could be directed to other areas of health with greater efficiency. However, the need to assess the “economic” gain from alternative forms of care is reflected in the continuing development of economic evaluation methods and the increasing numbers of studies with health economic input. Compilers of clinical practice guidelines are also placing more emphasis on economic data. Economic evaluations of interventions are central to informing the advice and decisions issued by organizations such as the UK’s National Institute for Clinical Excellence. That is, organizations are concerned with issues of cost-effectiveness and cost-benefit. One of the foremost organizations in the pursuit of rigorous evidence on the effectiveness of interventions is the Cochrane Collaboration – an international organization with the aim of improving the effectiveness of health care throughout the world by preparing, maintaining and making accessible systematic reviews of the effects of health care.

Economic assessments have become an integral part of policy decisions on healthcare, because expenditures on health care in developed countries have risen faster. Consequently, health-care expenditure has been consuming an ever-larger share of the

total economy, and politicians have to balance the optimum level of expenditures on health care. Economic evaluation can assess whether one particular intervention is worth undertaking compared to another intervention (or compared to doing nothing). Economic evaluation analyzes whether the additional benefits of an intervention are greater than the additional costs. In economic analyses, costs are typically categorized as “direct medical”, “direct non-medical”, and “indirect costs of lost productivity”. In financial or accounting analyses, costs are classified differently, as “variable” or “fixed”. Variable costs, such as the physician’s time and drugs administered, vary dependent on the numbers of cases treated, whereas fixed costs do not vary in the short-to medium term and are unlikely to change with any fluctuations in the number of cases (e.g., the cost of a building). Some health economists do use accountancy terms such as “fixed costs” but this is not a serious problem so long as the costs that are included are those appropriate for the perspective chosen and reflect the opportunity costs (Meltzer 2001). The maximum possible reduction in a disease due to the use of an intervention is termed the efficacy of the intervention. Efficiency evaluates how well resources are used to achieve a desired outcome. It has a number of different aspects: allocative efficiency measures the extent to which resources are allocated to the groups or individuals who can benefit most. For example, the benefits of urgent endoscopy provided in the first two hours to high-risk patients are far in excess of the benefits that arise when it is done in low-risk patients; allocative efficiency therefore requires the high-risk patients to be targeted as a priority, resulting in an improved level of health associated with very early emergent endoscopy; technical efficiency measures either the extent to which resources are combined to achieve maximum outcome, or alternatively the minimum amounts of resources that are combined to achieve a given outcome (for example, identifying the least expensive way to effectively treat a bleeding peptic ulcer; in this case, doing an unnecessarily second-look endoscopy or long courses of drugs or unnecessarily expensive drugs implies the existence of technical inefficiency.

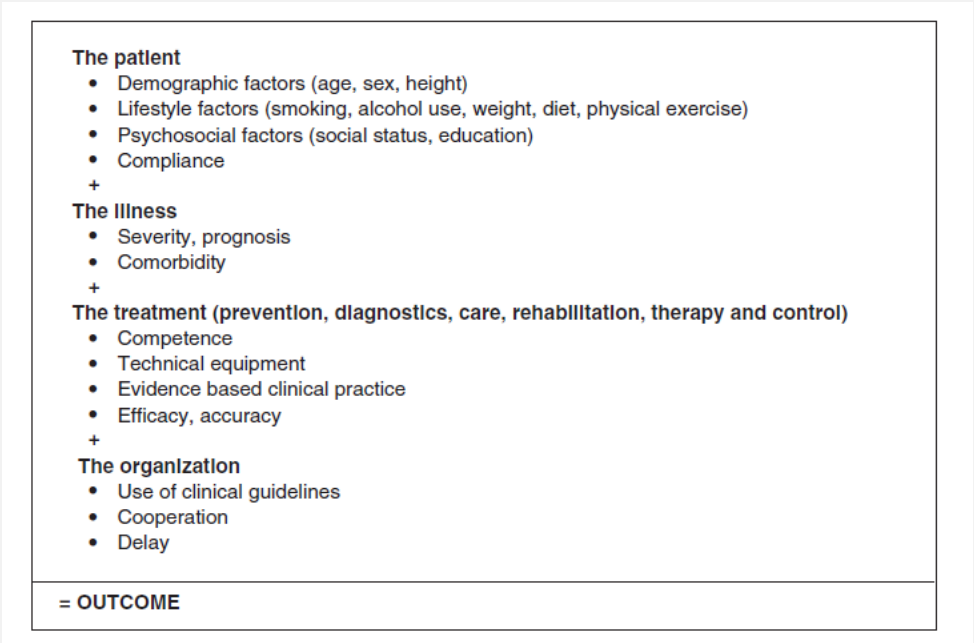
Since the objective of economic appraisal is to seek efficient and equitable uses of resources it is important that all potentially efficient and equitable options should be examined. The options examined have to be selected as being those considered to offer the greatest potential. This again emphasizes how economic appraisal builds on epidemiological evaluation and clinical trials. For example, an economic appraisal of an out-of-hours endoscopy program in the North of Portugal, could examine the alternatives of: no program; a large regional program; a program for old people only; for one city; for every city; for three cities; a program for one or two year; a program phased over several years. Ultimately the appraisal objective is to seek social efficiency and equity. However, when there is a constraint on the resource budget, seeking the most technically efficient

(maximum benefit) way of spending will be the objective. Where there is a fixed benefit or health effect to be achieved, the objective is to seek the most technically efficient—i.e. least cost—way.

Economic evaluation uses information on the costs and outcomes of different treatments to guide choices among competing demands for health care resources. We have limited resources, so have to choose between health services; health economics offers systematic ways to guide these choices. The three main methods used to assess the economics of an intervention in healthcare are: cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and cost-utility analysis (CUA). The central purpose of CEA is to compare the costs and the values of different health care interventions in creating better health and longer life. Many new medical devices, procedures, diagnostic tests, and prescription drugs are expensive; cost-effectiveness analysis can help to evaluate whether the improvement in health care outcomes justifies the expenditures relative to other choices. This understanding of the costs and outcomes of comparative interventions is essential for decision makers to make informed decisions about using health care resources efficiently. Questions of technical efficiency are addressed using CEA. The CBA in health care is the analysis of health care resource expenditures relative to possible medical benefit. This analysis may be helpful and necessary in setting priorities when choices must be made in the face of limited resources. This analysis is used in determining the degree of access to, or benefits of, health care to be provided. A particular form of CEA that is becoming more widespread in health care is where the benefits/health effects are expressed in terms of ‘quality-adjusted-life-years’ (QALYs) gained. This particular form of CEA is called CUA. In CUA the health effects of a project are expressed on a 0–1 scale of quality adjusted life for each time period, and the tangible outcomes/resource consequences in monetary terms. The overall effects of projects are set in terms of ‘cost per QALY gained’.

In conclusion, quality of care is a complex interaction between processes of care, clinical and patient oriented health outcomes and the productivity of a health care system (figure 4).

Figure 4: Factors determining the outcome of care in health care delivery



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CHAPTER II

BACKGROUND

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II. BACKGROUND

IIb. Non-Variceal Acute Upper Gastrointestinal Bleeding

NVAUGIB is a prevalent, clinical significant and expensive healthcare problem. It is the leading cause of urgent gastroenterology consultations and despite considerable advances during the last decades, NVAUGIB remains one of the most serious and potentially life-threatening medical cases that require hospitalization and careful monitoring of the patients (Gilbert 1990; Longstreth 1995; Rockall, Logan et al. 1995; Rockall, Logan et al. 1996).

Bleeding may be caused by many different lesions of variable prognostic importance. AUGIB is categorized as NVAUGB or variceal, depending on the aetiology. The vast majority of AUGB is secondary to non-variceal causes, with peptic ulcers being the most prevalent cause, followed by gastroduodenal erosions, Mallory-Weiss tear, esophagitis and Dieulafoy's lesions.

NVAUGIB is expected to rise with older demographics and the increased consumption of many drugs, such as non-steroidal anti-inflammatory drugs[6,7]. These drugs intensify the risk of peptic ulcer complications, mainly bleeding, in patients with a peptic ulcer history. Elderly patients constitute a subgroup with special characteristics who need careful handling during their hospitalization, because it is a population with considerable co-morbidity, higher medication use and greater risk for further complications. Validated prognostic scoring systems, based upon the severity of bleeding, diagnosis, endoscopic findings and extent of co-morbidities, predict mortality and have clinical utility[8,9]. Approximately 45%-60% of the admissions for AUGIB worldwide are due to peptic ulcers.

The treatment of NVAUGIB is based upon cardiovascular resuscitation followed by endoscopic therapy in patients with active bleeding or major stigmata of recent haemorrhage. Emergency surgery is undertaken for uncontrolled bleeding or re-bleeding that cannot be controlled by further endoscopic therapy. Early endoscopy (within the first 24 hours for NVAUGB) with risk classification by clinical and endoscopic criteria, allows for safe and prompt discharge of patients classified as low risk, improves patient

outcomes for patients classified as high risk, and reduces use of resources for patients classified as either low or high risk.

NVAUGIB can be defined in three words: common, costly, and potentially life-threatening. So it must be managed promptly and appropriately to be effective and prevent adverse outcomes. Balancing these roles in the light of increasing patient volume, ageing population and limited resources we face a new challenge in the emergency setting.

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II. BACKGROUND

IIb. Non-Variceal Acute Upper Gastrointestinal Bleeding

IIb1. Occurrence and Mortality Trends

AUGIB is the commonest cause of acute hospital admission to gastroenterology and therefore has a large impact on the acute medical admission workload. Changes in management have been shown in randomized controlled trials to improve outcome from gastrointestinal hemorrhage, but the largest observational studies of mortality trends following upper gastrointestinal hemorrhage report no improvement in overall mortality over the last 2 decades (van Leerdam, Vreeburg et al. 2003; Thomopoulos, Vagenas et al. 2004; Targownik and Nabalamba 2006; Loperfido, Baldo et al. 2009). The population-based study of patients hospitalized because of gastrointestinal complications in 10 general hospitals between 1996 and 2005 in Spain, performed by Lanas et al. (Lanas, Garcia-Rodriguez et al. 2009), demonstrated a progressive change in the overall picture of gastrointestinal bleeding (GI) events leading to hospitalization, with a clear decreasing trend in upper GI events and a significant increase in lower GI events, causing the rates of these two GI complications to converge. Overall, mortality has also decreased, but the in-hospital case fatality of upper or lower GI complication events has remained constant. According to the author, it will be a challenge to improve future care in this area, as well as reducing their associated mortality. Another study, from Netherlands, also examined time trends in incidence and outcome of upper GI bleeding (van Leerdam, Vreeburg et al. 2003). They reported that incidence decreased from 61.7/100,000 in 1993/94 to 47.7/100,000 persons annually in 2000, corresponding to a 23% decrease in incidence after age adjustment (95% CI = 15-30%). The incidence was higher among patients of more advanced age. However, rebleeding (16% vs. 15%) and mortality (14% vs. 13%) did not differ between the two time periods. Also, among patients with ulcer bleeding, rebleeding (22% vs. 20%) and mortality (15% vs. 14%) did not differ between the two time periods. Increasing age, presence of severe and life-threatening comorbidity, and rebleeding were associated with higher mortality. Another study from Greece, compared the etiology and clinical outcome of AUGIB, between two distinct periods, during 15 years: 668 patients hospitalized with the problem in 1986-1987 were compared to 636 patients with AUGIB in 2000-2001. Overall mortality was also reduced from 5.2% to 3.1% and in peptic ulcer bleeding patients from 3.3% to 2.4%, respectively, but the differences were not statistically significant (Thomopoulos, Vagenas et al. 2004). Also a Greek study,

estimated the incidence of AUGIB and peptic ulcer bleeding (PUB) in two different periods, 1995 and 2005. A reduction in the incidence of AUGIB from 162.9/100,000 population in 1995, to 108.3/100,000 population (rate ratio=0.49, confidence interval 95%=0.37-0.63) in 2005 and in the incidence of PUB from 104.8/100,000 population to 72.5/100,000 (rate ratio=0.49, confidence interval 95%=0.35-0.68) were, respectively, observed. The authors concluded that although the incidence of AUGIB significantly decreased, patients were older with more comorbidities, and mortality remained unchanged (Theocharis, Thomopoulos et al. 2008). The French also evaluated the main changes in characteristics, practices and outcome between 1996 and 2000 in patients admitted for an acute upper gastrointestinal hemorrhage (variceal and non-variceal hemorrhage); they observed a significant decrease in AUGIB mortality in the whole group (11.7 versus 7.2%; P=0.03), and particularly in the subgroup of cirrhotic patients (19.5 versus 11.1%; P=0.05) whatever the source of their bleeding (Di Fiore, Lecleire et al. 2005). A retrospective non-randomized clinical study performed during 2011 that took place at the Regional Institute of Gastroenterology and Hepatology in Cluj Napoca, revealed an important decrease in the need for urgent haemostatic surgery despite a relatively constant general mortality rate. Comparing data from 2011 with data from 2002 in the same hospital, they noticed a decrease by half for urgent haemostatic surgery in cases of non-variceal bleeding. In 2002, the need for urgent haemostatic surgery was 7.9% for non-variceal bleeding with a drop from 17% in 1989. In 2011, need for urgent surgery was 3.68%. The mortality rate was similar to previously data, reaching approximately 10%, remaining constant (Botianu, Matei et al. 2013). A single-center study from Italy, compared 587 patients who presented with AUGIB during the 1983-to-1985 period, with 539 patients in the 2002-to-2004 period. The overall incidence of AUGIB decreased from 112.5 to 89.8 per 100,000/y, which corresponds to a 35.5% decrease after adjustment for age (95% CI, 24.2%-46.8%). The age standardized incidence of ulcer bleeding decreased by 41.6% (95% CI, 27.2%-56%); the decrease occurred only in people younger than 70 years of age. Rebleeding rates decreased from 32.5% to 7.4% ($P < .001$) and surgery from 10.2% to 2.0% ($P < .001$). Overall mortality decreased from 17.1 to 8.2 per 100,000/y, which corresponded to a 60.8% decrease after adjustment for age (95% CI, 46.5%-75.1%). The age standardized mortality rate for ulcer bleeding decreased by 56.5% (95% CI, 41.9%-71.1%). The explanation for these data was that, advances in medical practice in recent decades have influenced the etiology and management of AUGIB (Loperfido, Baldo et al. 2009). In 2007, a study from Canada, confirmed the decrease in incidence from NVAUGIB; between 1993 and 2003, NVUAGIB incidence decreased from 77.1 cases to 53.2 per 100,000/y for the broad definition, and from 52.4 to 34.3 cases per 100,000/y for the narrow definition (ICD-9/ICD-10-based definition).

Although the proportion of NVAUGIB subjects requiring surgical intervention declined over the 10 years from 7.1% to 4.5%, the mortality rate remained steady at approximately 3.5%; but they only identified deaths that occurred before discharge (Targownik and Nabalamba 2006). The low mortality identified in this study (3.5%) is similar to other North American (Zhao Y.) and Mediterranean (Lanas, Garcia-Rodriguez et al. 2009) studies but is much lower than the European studies previously cited (van Leerdam, Vreeburg et al. 2003; Di Fiore, Lecleire et al. 2005; Loperfido, Baldo et al. 2009; Botianu, Matei et al. 2013). So, the studies with mortality reduction did not report variceal and non-variceal hemorrhage mortality trends separately or trends in different age and comorbidities. Other non-variceal hemorrhage studies from Spain, The Netherlands, Greece, Romania and France, with the exception of the Italian one, did not identify reductions in non-variceal inpatient mortality. Although these were large studies, none of them identified deaths that occurred after discharge because outcome was just analyzed in terms of in-hospital death.

More recently, a case control study, estimated trends in 28-day mortality in England following hospital admission for gastrointestinal hemorrhage. They used a case-control study design to analyze data from all adults administered to a National Health Service hospital, for upper gastrointestinal hemorrhage, from 1999 to 2007 (n=516,153). Cases were deaths within 28 days of admission, and controls were survivors to 28 days. The 28-day mortality was derived from the linked national death register. A logistic regression model was used to adjust trends in non-variceal and variceal hemorrhage mortality for age, sex, and comorbidities and to investigate potential interactions. The mortality in this study improved right up to the end of the study period. The authors clarified some reasons for the reduction in mortality: there were similar reductions in mortality whether or not an endoscopy was recorded and for all associated diagnoses, implying that endoscopic therapy was not a major contributor to the reduction in mortality; that improvement in standard non-endoscopic care has led to improved survival, such as the routine administration of intravenous proton pump inhibitor infusions, the routine use of risk scoring, the implementation of standardized clinical guidelines, and the subsequent local auditing of practice (Palmer 2002; Gralnek, Barkun et al. 2008; 2010; Barkun, Bardou et al. 2010).

It is important to notice that differences in practice may confound comparisons between countries. Even in the same country, variability in patient's management is observed (Hearnshaw, Logan et al. 2010). Nevertheless, an European Survey of Nonvariceal Upper Gastrointestinal Bleeding (ENERGIB) concluded that differences in outcomes of

NVAUGIB reported across countries did not seem to be due to differences in clinical management or health organizations, at least within a European setting (Lanas, Aabakken et al. 2011). ENERGIB was an observational, retrospective cohort study carried out across multiple centers in seven countries (Belgium, Greece, Italy, Norway, Portugal, Spain and Turkey). A target sample size of 400 patients per country was established and 123 centers participated in the study, with the following distribution per country: Belgium (26 centers), Greece (10), Italy (11), Norway (16), Portugal (12), Spain (24) and Turkey (24). A total of 2664 patients were included in the study, and 2660 patients were eligible for the statistical analyses. They evaluated a number of variables possibly associated with outcomes of NVAUGIB including clinical predictors, management strategies and healthcare resource utilization in a 'real-world', European, clinical practice setting. This report focused on the predictors of poor outcomes of NVAUGIB in terms of bleeding continuation/re-bleeding and mortality. Overall, 12.3% of patients experienced bleeding continuation/re-bleeding within 30 days of the initial NVAUGIB episode. Continued bleeding was observed in 7.3% of patients, while 10.5% of patients experienced re-bleeding within 30 days. The proportion of patients undergoing surgery (other than endoscopy) to control bleeding was low, at 3.3%. The mortality rate within 30 days of the bleeding event was 5.2%. The ENERGIB study therefore confirmed that mortality associated with NVAUGIB has not decreased substantially in recent years, despite advances in endoscopic and pharmacological therapies. There are some methodological limitations in this retrospective study that must be considered: all patients were treated according to the standard clinical care protocol at each participating study site; the practice of retrospective collection of data through clinical records, make it particularly difficult to check and unreliable. Other factors that have been linked to fatality rates in AUGIB such as, social deprivation or day of the week of hospitalization, have not been considered (Lanas, Aabakken et al. 2011). It is difficult to understand how different processes produced similar outcomes. If this was the question this time round, the answer came afterwards. In 2012, Lanas et al. tackled the problem of variability in the management of NAVUGIB in Europe by effectively identifying the processes (Lanas, Aabakken et al. 2012). The results showed a wide between-country variability in the area and specialty of the NAVUGIB management team and unit transfer rates after the initial hospital assessment. The mean time from admission to endoscopy was <1 day only in Italy and Spain. Wide variation in the use of pre-endoscopy (35.0-88.7%) and relatively consistent (86.5-96.0%) post-endoscopic pharmacological therapy rates were observed. There was substantial by-country variability in the rate of therapeutic procedures performed during endoscopy (24.9-47.6%). NVAUGIB-related healthcare resource consumption was high and variable (days hospitalized, mean 5.4-8.7 days; number of

endoscopies during hospitalization, mean 1.1-1.7). The authors concluded that ENERGIB demonstrated that there were substantial differences in the management of patients with NVAUGIB episodes across Europe, and that in many cases the guideline recommendations for the management of NAVUGIB were not being followed.

A total of 404 Portuguese patients from twelve hospitals, with NVAUGIB were included in ENERGIBE study, with a mean age of 68.5±17.1 years. The clinical risk score evaluated by the expected clinical risk scales (Rockall, Blatchford or ASA scales) was not registered in any of the Portuguese patients' clinical records. The mortality rate was 4.8% and, only in four cases, was directly related to the bleeding episode. Data were collected retrospectively from patients' medical records and so, many data were missed, like the endoscopy timeframe (Fonseca, Alves et al. 2012). Another retrospective Portuguese study, analyzed data from 597 patients admitted with AUGIB between August,1974 and August,1979 and reported a mortality rate of 10% and 6% for AUGIB and NVAUGIB, respectively (Carlos Sofia 1981). A prospective, six year study, to evaluate the adequacy of a simple "Numerical Risk Score", proposed by the National Audit of Acute Upper Gastrointestinal Hemorrhage (United Kingdom), for a population of 372 high risk patients admitted to a Gastroenterological Intensive Care Unit with peptic ulcer bleeding, was conducted in Portugal and published in 1999. The mortality rate was 3,4%, 9,7% and 19,4% for ward inpatients, intensive care patients and surgery patients, respectively (José Manuel Romãozinho and Ernestina Camacho 1999). I am unaware that there are more studies published in Portugal.

The results of 1402 surveys of emergency physicians, internists, and gastroenterologists practicing in USA hospitals were as follows: there was no difference in the application of the quality indicators by specialty or clinical position. Among all physicians, 53% had ever heard of and 30% had ever used a risk score. More gastroenterologists than non-gastroenterologists had heard of (82% vs. 44%, $P<0.001$) and used (51% vs. 23%, $P<0.001$) a risk score. There was no difference between attending physicians and trainees. Gastroenterologists and attending physicians more often cited lack of utility as a reason to not use risk scores, whereas non-gastroenterologists and trainees more often cited lack of knowledge. They concluded that, although the agreement with AUGIB initial management guidelines was high but adherence-especially pertaining to the use of risk scores was low (Liang and Saltzman 2014).

So, in general, the failure to demonstrate a clinical improvement in NVAUGIB may be due to, either clinical guidelines not being followed or patient's characteristics have changed.

This latter explanation, with increasing age and comorbidity has been proposed as the likely explanation. For instance, if in some acute emergencies, such as heart attacks, the most common cause of death relates to the associated cardiovascular disease, but in other emergencies, such as stroke, death is commonly associated with other causes, such as cardiovascular disease and respiratory infections (Bronnum-Hansen, Jorgensen et al. 2001; Vernino, Brown et al. 2003).

However, despite NVAUGIB being one of the most common gastroenterology reasons for admission in acute medicine, the outcomes of patients who have experienced a NVAUGIB episode are poorly understood in the context of the process of care. Therefore, to identify which interventions may possibly reduce mortality, we must analyze the impact of several factors in health care delivery system, which may vary from system to system.

CHAPTER II
BACKGROUND

IIa. Quality in Health Care
IIa1. Definition and Dimensions of Quality
IIa2. Quality Assessment and Improvement
IIa2.1. The History of Quality Improvement
IIa2.2. Assessing and Measuring Quality in Healthcare

IIb. Non-Variceal Acute Upper Gastrointestinal Bleeding
IIb1. Occurrence and Mortality Trends
IIb2. Interventions That Work
IIb3. Interventions That Need More Study: controversies and areas of uncertainty

II. BACKGROUND

IIb. Non-Variceal Acute Upper Gastrointestinal Bleeding

IIb2. Interventions That Work

As we have shown, although some data suggest a reduction in the incidence, the clinical burden and economic costs of NVAUGIB remain high (van Leerdam, Vreeburg et al. 2003; Ahsberg, Ye et al. 2011; Lanas, Garcia-Rodriguez et al. 2011).

The initial assessment is to determine whether the patient requires urgent intervention (e.g., endoscopic, surgical, transfusion) or can undergo delayed endoscopy or even be discharged to outpatient management.

Although numerous factors from the patient history, physical examination, and initial tests have been examined for an association with a need for intervention, no single factor is sufficiently predictive of NVAUGIB severity to be used for triage. The most predictive individual factors are a history of malignancy or cirrhosis, (Adamopoulos, Baibas et al. 2003) presentation with hematemesis, (Adamopoulos, Baibas et al. 2003; Aljebreen, Fallone et al. 2004) and signs of hypovolemia including hypotension, (Stoltzing, Ohmann et al. 1991; Adamopoulos, Baibas et al. 2003) tachycardia and shock, and a hemoglobin <8 g/dL. (Adamopoulos, Baibas et al. 2003; Aljebreen, Fallone et al. 2004) Some factors, such as a history of aspirin or no steroidal anti-inflammatory use, may not be useful for immediate disposition but are still important to assess for future management [e.g., if peptic ulcer disease] (Stoltzing, Ohmann et al. 1991).

Patients who have significant comorbidities may require admission regardless of the severity of the NVAUGIB.

In fact, many risk factors are associated with bleeding, and these must be addressed.
Endoscopic intervention reduces the rate of rebleeding, the need for surgical intervention, and mortality in high-risk patients.

CHAPTER II
BACKGROUND

IIa. Quality in Health Care
IIa1. Definition and Dimensions of Quality
IIa2. Quality Assessment and Improvement
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IIb. Non-Variceal Acute Upper Gastrointestinal Bleeding
IIb1. Occurrence and Mortality Trends
IIb2. Interventions That Work
IIb3. Interventions That Need More Study: controversies and areas of uncertainty

II. BACKGROUND

IIb. Non-Variceal Acute Upper Gastrointestinal Bleeding

IIb3. Interventions That Need More Study: controversies and areas of uncertainty

There are a few issues that are still unresolved with regard to the patient's assessment, pré-endoscopic and endoscopic:

Risk Stratification Scoring System

The most consistently reported predictors of mortality and re-bleeding in NAVUGIB have been age, number of comorbid conditions and hemodynamic instability (Barkun, Bardou et al. 2003; Marmo, Koch et al. 2008; Lanas, Aabakken et al. 2011), but, in order to standardize and improve care, various scoring systems have been developed to identify those individuals at high risk of requiring treatment, rebleeding or death. Early stratification of patients into high and low-risk categories allows the identification of individuals who may benefit from earlier interventions or those who can safely be discharged after endoscopy (Gralnek, Barkun et al. 2008; 2010; Barkun, Bardou et al. 2010). The International Consensus Recommendations on the management of patients with NVAUGIB recommend “early risk stratification”, by using validated prognostic scales in all patients (Barkun, Bardou et al. 2010; Sung, Chan et al. 2011).

There are well-validated risk stratification scoring systems in the setting of NVAUGIB that helps to stratify patients into low-risk or high-risk patients, thus, influencing decisions regarding hospitalization versus prompt safe discharge from the emergency department (ED), and possibly influencing the ideal time to perform endoscopy (Laine and Jensen 2012). There are two types of scores: those requiring endoscopy and those not requiring endoscopy (table 5).

The Rockall score, described in 1996 following analysis of data from a large English audit, can be calculated using both pre-endoscopic [clinical Rockall; total = 7] and post-endoscopic data [total = 11]. The full Rockall score incorporates both pre- and post-endoscopic parameters. It predicts risk for further bleeding and mortality using age [<60, 60-79, and >70 years], the presence of shock [systolic blood pressure <100 mmHg and

heart rate >100 beat/min], comorbidities [ischemic heart disease, congestive heart failure, any major comorbidities; and renal or liver failure and disseminated malignancy], and endoscopic diagnosis [Mallory–Weiss tear, peptic ulcer, erosive disease, esophagitis, or evidence of malignancy], along with endoscopic findings [blood in stomach, adherent clot, visible vessel, and spurting vessel or pigmented spot or no stigmata] (Rockall, Logan et al. 1996). Patients with risk scores of 0 and 1 have low incidences of rebleeding and no associated mortality; allowing the identification of patients at low risk of complications for early discharge (Rockall, Logan et al. 1996). Is the most widely used scoring system, validated by several studies. The Glasgow Blatchford score (GBS) was developed to predict the need for intervention in UGIB, that is, transfusions, endoscopic therapy, and surgery. It's a non-endoscopy score, using only clinical and laboratory data (Blatchford, Murray et al. 2000). The American Baylor score was developed in 1993 to predict rebleeding after endoscopic therapy and includes five clinical and endoscopic variables (Saeed, Winchester et al. 1993). The Cedar Sinai predictive index predicts outcome and length of hospital stay; it includes endoscopic findings, hemodynamics, comorbidities and time from symptoms (Hay, Maldonado et al. 1997). The Almela score was developed to identify a low risk group suitable for out-patient management(Almela, Benages et al. 2004). The Italian score was developed to predict mortality (Marmo, Koch et al. 2010). At present, the Rockall score is the most widely used and studied post-endoscopy score to predict outcome.

The GBS was developed in 2000 to predict the need for hospital based intervention (transfusion, endoscopic therapy, or surgery) or death (Blatchford, Murray et al. 2000). Romagnuolo et al. described a modified GBS (excluded serum urea and a history of syncope), easier to use in clinical practice (Romagnuolo, Barkun et al. 2007).

The Cambridge score requires 14 clinical and laboratory variables and has not been externally validated (Cameron, Pratap et al. 2002).
The AIMS65, a simple risk score has been developed and validated (Saltzman, Tabak et al. 2011; Chandra 2013; Hyett, Abougergi et al. 2013). The following parameters are used: age less than 65 years, systolic blood pressure 90 mmHg or lower, altered mental status, albumin less than 3.0 g/dL, and INR greater than 1.5. For those with no risk factors, the mortality rate was 0.3% compared with 31.8% in patients with all 5 (P < 0.001).

The GBS and the Clinical Rockall score have been examined in several studies and may determine the need for urgent endoscopy. In 3 studies comparing clinical prediction rule

scores in the same study population, the GBS performed better than the Clinical Rockall score for predicting patients at high risk for clinical intervention (Chen, Hung et al. 2007; Stanley, Ashley et al. 2009; Srirajaskanthan, Conn et al. 2010). A systematic review and quantitative appraisal of 16 prediction scores in gastrointestinal bleeding, concluded that methodological quality was suboptimal (de Groot, Bosman et al. 2012). The authors suggested that clinicians should use the "best available" scores according to performance and quality, until new prediction scores of higher quality have been developed. These include, the GBS for predicting whether an intervention for acute gastrointestinal bleeding is required and, the scores of Villanueva et al. (Villanueva, Balanzo et al. 1993), Guglielmi et al. (Guglielmi, Ruzzenente et al. 2002) , and Chiu et al. (Chiu, Ng et al. 2009) for predicting a poor outcome, rebleeding rate, and mortality, respectively, according to endoscopic features. The results of this systematic review emphasized the need for high quality prediction scores in gastrointestinal bleeding.

In conclusion, stratification of the risk of complication or death can optimize management and improve patient outcomes, while ensuring adequate resource allocation. The ideal prognostic score should be accurate, simple, reproducible, and prospectively validated in different populations. Published scores meet these requirements only partially, and thus can only be used as part of an integrative diagnostic and therapeutic process.

Table 5: Risk Stratification Scoring Systems.

	Endoscopy Required?	Number of Variables	Predicts
Full Rockall	Yes	6	Rebleeding and Mortality
Baylor	Yes	5	Rebleeding after endoscopic therapy
Cedars Sinai	Yes	6	Outcome and length of hospital stay
Almela	Yes	3	Early discharge
PNED *Progetto Nazionale Emorragie Digestive*	Yes	10	Mortality
Admission Rockall	No	4	Early discharge
Glasgow Blatchford	No	8	Need for hospital based intervention and mortality
Modified Blatchford	No	5	Need for hospital based intervention and mortality
AIMS65	No	5	Mortality

Modified from Adrian J Stanley, World J Gastroenterol 2012

The Optimal Timing For Endoscopy

Endoscopy has a clearly-defined role in the primary management of NVAUGIB (Hwang, Fisher et al. 2012). The endoscopic haemostatic therapy for NVAUGIB is indicated for patients having ulcers with high risk bleeding stigmata such as active bleeding or no bleeding visible vessels. The endoscopist can choose the haemostatic method according to the type, size, ulcer base characteristics, and location of the lesion. Injection therapy using epinephrine, ethanol, or hypertonic saline, thermal coagulation using contact and noncontact devices has been common choices in NVAUGIB with good outcomes. Endoscopic mechanical modalities currently available can provide secure bleeding control in most cases. Endoscopic hemostasis using a combination of currently available methods is preferred to monotherapy, especially to injection therapy alone, considering the synergistic effect of each modality having different mechanism of action.

Appropriate indications for some therapeutic endoscopic interventions are well established and there has recently been increasing consensus regarding when and how the various methods for controlling bleeding should be deployed. But, although timing of endoscopy plays an important role in the diagnosis, risk stratification and treatment of AUGIB, the optimal timing for this investigation is still unclear. Service provisions for out-of-hours endoscopy are highly variable, and offering 24-hour endoscopy across all institutions may have serious economic implications. Evidence-based consensus guidelines recommend endoscopy within 24h (Barkun, Bardou et al. 2010; Laine and Jensen 2012). Very early endoscopy [<12 h] when compared with early endoscopy [>12 h and < 24 h] does not seem to confer any additional benefits in terms of rebleeding, need for surgery, or mortality in unselected patients with NVAUGIB based on randomized trial findings (Lin, Wang et al. 1996; Bjorkman, Zaman et al. 2004; Lim, Ho et al. 2011). However, Lim et al*.,* suggested, using observational data, that endoscopy within 13 h of presentation was associated with a lower mortality in selected high-risk patients, defined as GBS > 12 (Lim, Ho et al. 2011). So, although some authors propose that endoscopy should be carried out within 12 h in acutely ill patients, this is supported by limited data (Lin, Wang et al. 1996; Lim, Ho et al. 2011) and is currently controversial (Barkun, Bardou et al. 2012). Furthermore, early endoscopy may identify those patients who can be safely discharged immediately after endoscopy, or, when combined to other factors, promptly and safely discharge patients already hospitalized (Forssman 1976; Moreno, Jaurrieta et al. 1998; Chaparro, Barbero et al. 2010; Rotondano, Cipolletta et al. 2014). In fact, early endoscopy within 24 h of presentation following successful resuscitation is recommended for patients with NVAUGIB (Barkun, Bardou et al. 2010). A recent review aimed to evaluate the

optimal timing of early endoscopy by examining the findings of randomized clinical trials and retrospective cohort studies that used comparable outcome measures and have been reported in the literature (Tsoi, Ma et al. 2009). Of the 1,498 studies they have identified through database searches, the discussion was based in the review of three randomized, controlled trials (Lin, Wang et al. 1996; Lee, Turnipseed et al. 1999; Bjorkman, Zaman et al. 2004) and five retrospective cohort studies (Cooper, Chak et al. 1998; Cooper, Chak et al. 1999; Schacher, Lesbros-Pantoflickova et al. 2005; Tai, Huang et al. 2007; Targownik, Murthy et al. 2007). They found great heterogeneity in the study design, follow-up period, endoscopic therapy and adjuvant therapy in these eight studies. One crucial factor in the evaluation of timing for early endoscopy is whether hemodynamically unstable patients were excluded from the studies. Among the eight trials, two specifically excluded hemodynamically unstable patients (Lee, Turnipseed et al. 1999; Bjorkman, Zaman et al. 2004). Five studies included both stable and unstable patients (Lin, Wang et al. 1996; Cooper, Chak et al. 1998; Cooper, Chak et al. 1999; Schacher, Lesbros-Pantoflickova et al. 2005; Tai, Huang et al. 2007) and one study included only hemodynamically unstable patients (Targownik, Murthy et al. 2007). They concluded that early endoscopy (less than 2 to 6 h) showed no improvement in clinical outcomes compared with a delayed approach [less than 24 to 48 h] (Tsoi, Ma et al. 2009). This has also been reflected by a large prospective UK audit, that demonstrated that endoscopy within 12 h did not affect mortality or the need for surgery, but led to a decreased length of stay(Jairath, Kahan et al. 2012).

Concluding, we need to focus on tools which address major concerns like effectiveness, safety and costs, in order to achieve, from medical, endoscopic, and pharmaceutical intervention, improvement in outcomes and reduce medical costs, by reducing rebleeding, length of hospital stay and the need for surgical procedures. We have already set out our view of these issues (Pedroto, Dinis-Ribeiro et al. 2012).

CHAPTER III
RESEARCH METHODOLOGY

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IIIb. The Process

IIIc. Patients and Data Analysis

IIId. Statistical Analysis

CHAPTER III

RESEARCH METHODOLOGY

IIIa. Setting

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III RESEARCH METHODOLOGY

IIIa. Setting

Figure 5: The North of Portugal and URGE localization

From January 2010 to December 2012, a prospective observational study was conducted at the endoscopy unit of Centro Hospitalar do Porto (CHP), a 820-bed acute care, university hospital, serving, as an out-of-hours endoscopy center, an estimated population of 3.7 million (one third of the national population), with about 38 percent of the national youth population concentrated in the region (figure 5). The northern region includes eight sub-regions and an area of about 21.278 km² (24% of the continent). Since October 2006, in CHP, 30 consultant trained gastroenterologists from eight hospitals and sixteen skilled assistant staff from the endoscopy unit [eight nurses and eight endoscopy technicians] were integrated as the emergency team, everyday from 8 pm to 8 am; they are responsible for handling all gastroenterology emergencies, especially those requiring urgent endoscopy.

The objectives of the URGE are: to provide phone consultations during the night; to provide consultations on site and endoscopy. URGE receives around 800-1000 patients/year, being around 53% of the patients acute upper bleeders; a non-variceal cause accounts for approximately 52% of these. Each institution is accountable for the

remuneration for out-of-hours gastroenterology physician work, except for the assistant staff [nurse and endoscopy technician] that is the sole responsibility of the endoscopy unit of CHP. In this way, all are allocating human and financial resources. CHP has eight emergency teams and quarterly, the head of the gastroenterology department from five hospitals, is responsible for sending to the URGE coordinator the physicians rota, according to the teams which have been assigned to them; physicians from the smaller units strengthen some teams; this reflects 1 shift/physician/month. The provision of emergency endoscopy fulfills all the recommendations of the British Society of Gastroenterology**.** CHP has elective beds for bleeders in the acute medical or surgery units and two intensive care units.

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After the patient's arrival at the ED, they are taken care of firstly by ED staff; after the first-steps in the patient's care, the gastroenterologist is called and the emergency upper endoscopy (EGD) is performed by the gastroenterology staff. Referral patients are stabilized in the nearest hospital and transferred after agreement with the consultant gastroenterologist. When appropriate and safe, the procedure takes place in the endoscopy unit or in the emergency room or theatre. The decision to, where and when to perform EGD, diagnostic or therapeutic, is decided by the individual endoscopist, although he is guided by a regional protocol, which defines the need for therapeutic endoscopy according to international consensus statements (Barkun, Bardou et al. 2010; Laine and Jensen 2012). The endoscopist determines the level of anesthetic support. After the procedure, the patients are admitted or transferred back to their institution. Our practice is to perform EGD before discharge on all patients who have AUGIB and then, decide to, admit, discharge or transfer. In order to identify whether interventions might improve quality of care, the authors prospectively collected data, to investigate the outcomes of these patients and correlate them to the all process of care. We took several important steps: the first retrospective clinical audit, twelve months after the model's implementation, demonstrated weak adherence to important aspects of care and highlighted the areas that required improvement. In 2010, clinical guidelines, including safe transfer practice, for AUGIB were implemented and spread among all the northern institutions, whatever their level of care. They were reviewed and approved by the directors of all gastroenterology departments and published (I Pedroto and F Magro. Gestão Clínica da Hemorragia Digestiva Alta: Normas de Orientação Clínica. Conselho Diretivo da ARS-Norte, 2010-see appendix). Also, check sheets have been updated; the pilot test showed that the first was too long, with a large number of items; now a simple check sheet, that separates the process into sub steps, is fulfilled for all the bleeding patients: time of contact, time of arrival, hemodynamics, risk stratification, medication, time of endoscopy, time of discharge; nurses do part of this job. Data are filled out by the attending physician; nurses do part of this job (figure 6). In fact, the availability of appropriately trained and experienced endoscopy nursing support (a fixed team from the endoscopy unit of CHP) is an aspect of key importance. URGE receives around 800 patients/year, being 53% of the patients acute upper bleeders; 52% of these, bleed from a non-variceal cause. In northern Portugal, until October 2006, the out-of-hours management of AUGIB was dependent on the organizational structure of the each hospital, with great variability (8am-8pm every

day, no weekends, or 8am-24pm weekdays or 8am-24pm weekdays and weekend). The URGES' coordinator is responsible for checking the standardized-item list. The complete 30 days follow-up was ensured by analysis of the electronic database or by direct telephone contact. All the data are used to fulfill a framework for NVAUGIB, adapted from the British Society of Gastroenterology (tables 6 and 7).

Table 6: NVAUGIB: An Evaluation Framework (January 2010-December 2012)

How was the service used?

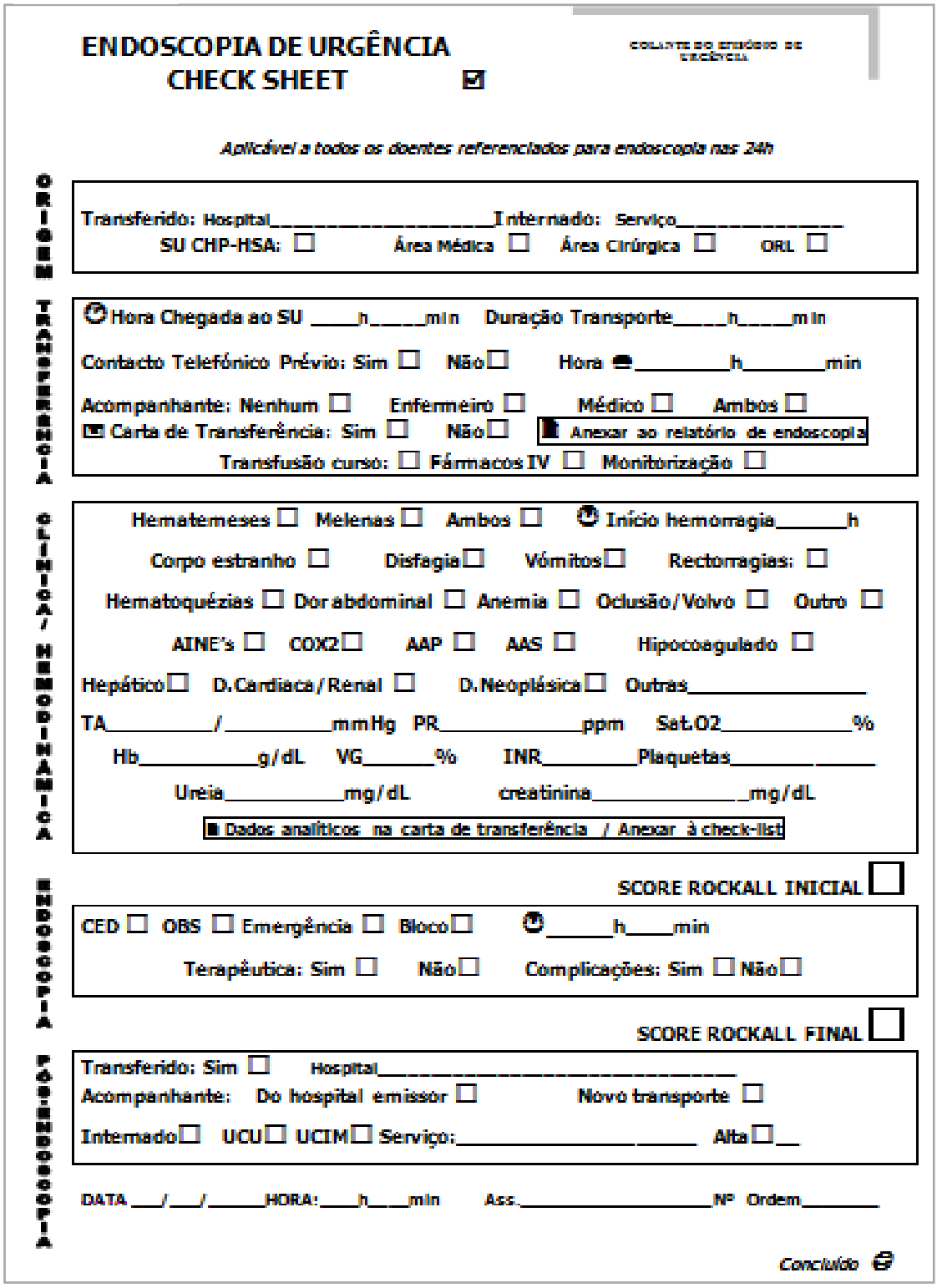
Evaluation Question	Dataset	Analysis
How many NVAUGIB patients?	Patients with NVAUGIB	Number of patients presenting in the evaluation period
Where do patients come from?	Source of referral: Local or inter-hospital transfer	Number and % of local vs. transfers
Where patients transferred after local agreement?	Time of referral (phone) Time of arrival to local service	Number and % of patients transferred after previous agreement Mean transfer time Mean time to arrival
When do patients present with NVAUGB?	Data and time of presentation with NVAUGIB	Distribution of times of presentation: • Year • Month • Day of the week • Time of the day • In-hours vs. out-of-hours • Weekday vs. weekend
Are patients referred appropriately for endoscopy?	Inappropriate referral: • not provided • no AUGIB If provided: • data and time • therapeutic intervention • inconclusive	Number and % of patients who met criteria of AUGIB Distribution of times to endoscopy Number and % of therapeutic endoscopy
What risk level presented the patients?	Risk levels of patients with NVAUGIB	Distribution of patients: • Low-risk • Moderate-risk • High-risk Adverse events: • during transfer • in-hospital • endoscopy Comorbidities Age Medication
How were patients managed after endoscopy?	Discharged Admitted as inpatients Inter-hospital transfer	Distribution of patients: • Admission • Transferred • Discharged

Table 7: NVAUGIB: An Evaluation Framework (January 2010-December 2012)

How was the service provided?

Evaluation Question	Dataset	Analysis
How many patients had endoscopy?	Date and time of endoscopy	Number and % of endoscopic procedures: • local • transfers
Was endoscopy timely?	Date and time of endoscopy	Distribution of times to endoscopy : • local • transfers
How many patients had therapeutic endoscopy?	Date and time of endoscopy	Number and % of endoscopic procedures: • local • transfers
How many patients had to repeat endoscopy (inconclusive)?	Patients with NVAUGIB	Number and % of patients: • local • transfers
How many patients rebled?	Source of referral: Local or inter-hospital transfer	Number and % of patients that rebled: • local • transfers
How many patients had surgery?	Date and time of procedure Indication for surgery	Number and % of patients who received surgery: • local • transfers
How many patients died from NVAUGIB?	In-hospital mortality 30 day mortality	According to: • local • transfers
How many patients died from other causes?	Patients with NVAUGIB	Cause of death

Figure 6



ENDOSCOPIA DE URGÊNCIA
CHECK SHEET ☑

Aplicável a todos os doentes referenciados para endoscopia nas 24h

ORIGEM

Transferido: Hospital_____ Internado: Serviço_____
SU CHP-HSA: ☐ Área Médica ☐ Área Cirúrgica ☐ ORL ☐

TRANSFERÊNCIA

Hora Chegada ao SU ____h____min Duração Transporte____h____min
Contacto Telefónico Prévio: Sim ☐ Não ☐ Hora _____h_____min
Acompanhante: Nenhum ☐ Enfermeiro ☐ Médico ☐ Ambos ☐
Carta de Transferência: Sim ☐ Não ☐ Anexar ao relatório de endoscopia
Transfusão curso: ☐ Fármacos IV ☐ Monitorização ☐

CLÍNICA / HEMODINÂMICA

Hematemeses ☐ Melenas ☐ Ambos ☐ Início hemorragia_____h
Corpo estranho ☐ Disfagia ☐ Vómitos ☐ Rectorragias: ☐
Hematoquézias ☐ Dor abdominal ☐ Anemia ☐ Oclusão/Volvo ☐ Outro ☐
AINE's ☐ COX2 ☐ AAP ☐ AAS ☐ Hipocoagulado ☐
Hepático ☐ D.Cardíaca/Renal ☐ D.Neoplásica ☐ Outras_____
TA_____/_____mmHg PR_____ppm Sat.O2_____%
Hb_____g/dL VG_____% INR_____Plaquetas_____
Ureia_____mg/dL creatinina_____mg/dL
Dados analíticos na carta de transferência / Anexar à check-list

SCORE ROCKALL INICIAL ☐

ENDOSCOPIA

CED ☐ OBS ☐ Emergência ☐ Bloco ☐ _____h____min
Terapêutica: Sim ☐ Não ☐ Complicações: Sim ☐ Não ☐

SCORE ROCKALL FINAL ☐

PÓS-ENDOSCOPIA

Transferido: Sim ☐ Hospital_____
Acompanhante: Do hospital emissor ☐ Novo transporte ☐
Internado ☐ UCU ☐ UCIM ☐ Serviço:_____ Alta ☐

DATA ___/___/_____HORA:____h___min Ass._____Nº Ordem_____

Concluído

CHAPTER III

RESEARCH METHODOLOGY

IIIa. Setting

IIIb. The Process

IIIc. Patients and Data Analysis

IIId. Statistical Analysis

III RESEARCH METHODOLOGY

IIIc. Patients and Data Analysis

Data on all consecutive patients, aged 18 and over, admitted directly to the emergency department of Centro Hospitalar do Porto (ED-CHP) or transferred from another institution, were prospectively collected. Patients with a new onset of NVAUGIB [clinical evidence of overt upper bleeding on admission or a history of hematemesis, coffee ground vomiting, melena, hematochezia, or a combination of any of these within 24h preceding admission] and with an upper endoscopy performed were included. Patients were excluded if they were younger than 18 years old, if endoscopy was not performed, had chronic anemia or bled as inpatients hospitalized for an unrelated illness. Demographic, clinical and endoscopic data from patients with NVAUGIB were collected and those with other sources of bleeding were excluded. Comorbidity was defined as the presence of any of the following diseases: (1) cardiac disease including ischemic heart disease and congestive heart failure; (2) hypertension; (3) chronic liver disease; (4) chronic renal disease; (5) vascular disorders including peripheral and central vascular diseases; (6) history of stroke; (7) diabetes; (8) malignancy; (9) metastatic malignancy; (10) renal or liver transplant; (11) hereditary bleeding disorder; (12) peptic ulcer disease, complicated or not. All medication, at time of presentation, was recorded. Patient workflow was examined: time of admission at the first hospital, time of first contact to the endoscopy unit, time of arrival to the endoscopy unit, time of endoscopic procedure, time of inpatient admission, discharge or transferred back to the first hospital; endoscopic lesion and therapy; adverse events (table 8). Mortality was defined as any death occurring during hospitalization or within 30 days of the index bleeding episode and considered as bleeding related (after uncontrolled bleeding; occurring within 24h after endoscopy; during surgery for uncontrolled bleeding; adverse events during endoscopy or surgery) or non-bleeding related (comorbidity or nosocomial infections). Rebleeding was defined as recurrent haematemesis, melena, with hemodynamic instability or a decrease in hemoglobin concentration of at least 2g/L and confirmed by a second endoscopy, recurring within 30 days.

Our primary variables were out-of-hours direct admissions to ED-CHP vs. out-of-hours transferred patients from another institution.

Table 8: Baseline characteristics of patients and data recorded

Symptoms / signs (hematemesis, melena, hematochezia)
Age
Gender
Prior upper gastrointestinal clinical events (e.g., bleeding, perforation)
Major current comorbidities
Key medications (NSAIDs, antithrombotics, and antisecretory)
Hemoglobin and hematocrit (at presentation)
Platelets, INR, urea, creatinin
Transfusions (number of units)
Timing of endoscopy (hours after presentation to the first hospital: CHP or other hospital)
Timing of first contact to the endoscopy tertiary referral regional endoscopy unit
Timing of arrival to the endoscopy tertiary referral regional endoscopy unit
Timing of admission or transfer or discharge, after endoscopy
Endoscopic Lesion
Stigmata of hemorrhage (Forrest classification)
Endoscopic therapy
Score from scoring system validated to predict outcomes (Rockall)
In-hospital rebleeding
30 day Readmissions
Surgery
30-day Mortality
Exclusion Criteria
Age under 18 years
Symptoms or signs of blood loss or anemia
Patients that did not undergo endoscopy for the following reasons: patients specifically categorized as terminal care patients; patients who refused or whose family refused to consent to endoscopy; patients self discharging prior to endoscopy being undertaken; patients requiring direct and urgent surgical intervention because of rapid exsanguination; patients with a specific contraindication to endoscopy; and patients who died rapidly on admission
Bleeding in patients already hospitalized for unrelated disease
Patients hospitalized in other clinics and presented just for endoscopy examination

CHAPTER III
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III RESEARCH METHODOLOGY

IIId. Statistical Analysis

Categorical variables were described as absolute frequencies (n) and relative frequencies (%). Median and percentiles or median and standard deviation were used for continuous variables. When testing a hypothesis about categorical variables a chi-square test and Fisher's exact test were used, as appropriate. In order to have a more thorough understanding of the factors associated, with mortality (in-hospital and 30 day) and rebleeding, univariate and multivariate logistic regression modeling was used. Factors that were significant in the univariate analysis at $p<0.2$ were included in the multivariate logistic regression models. Variables that have been previously identified to carry important prognostic significance in patients with NVAUGIH were included in the final multivariate model even if they didn't meet statistical significance on univariate analysis. Model discriminative power was evaluated by receiver-operator curve (ROC) curve analysis with confidence interval 95% (CI95%). The significance level used was 0.05. Statistical analysis was performed using the software Statistical Package for the Social Sciences v. 20.0.

CHAPTER IV
RESULTS

IVa. Overall Results
IVb. Main Results

CHAPTER IV
RESULTS

IVa. Overall Results

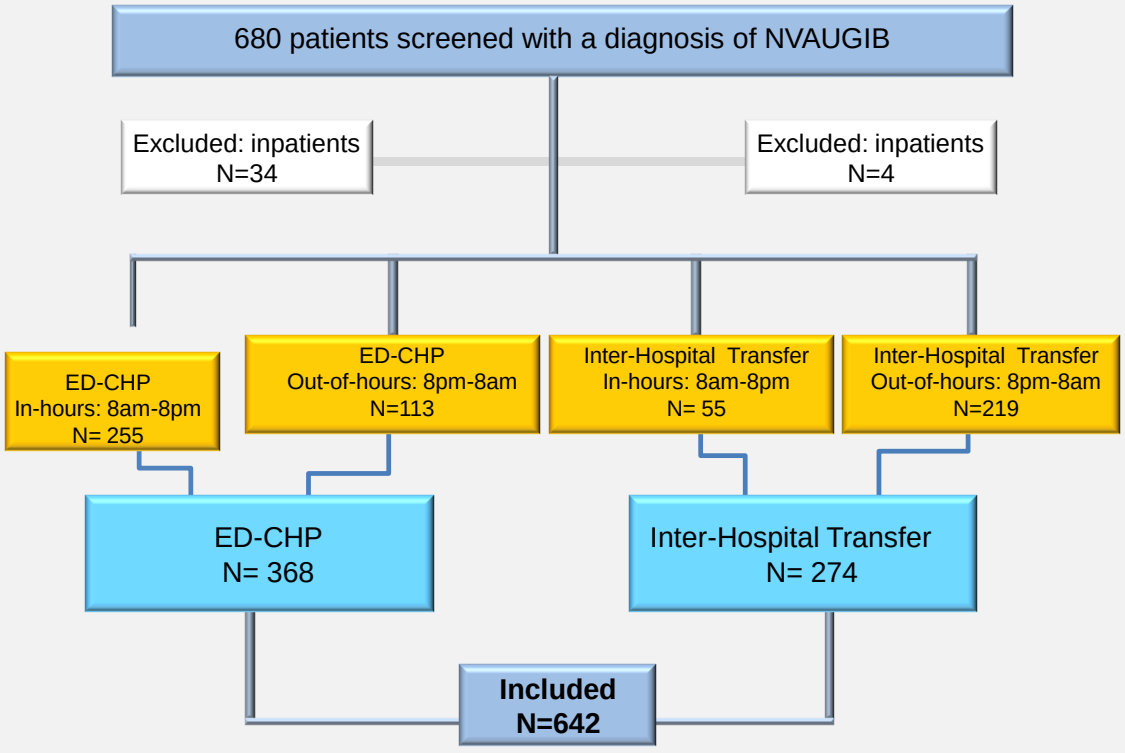
IVb. Main Results

IV. RESULTS

IVa. Overall Results

Data were collected from January 2010 to December 2012. All consecutive patients who had an endoscopic diagnosis of NVAUGIB were enrolled: 680 patients (53.4% men) were referred for endoscopy after previous contact with the gastroenterologist who agreed to receive the patient. We excluded 43 patients who bled as inpatients. Our study involved 368 patients who were directly admitted to the ED-CHP while 274 were transferred from other hospitals (figure 7). In CHP, similar to other hospitals, at admission, patients are managed by the emergency internists or surgeons.

Figure 7: Patient's enrollment beyween January 2010-December 2012



This flow chart details the patient enrollment in the study.

In the evaluation period, 642 patients with a mean age of 66 ±16,5 years (19-97 years) met the criteria of NVAUGIB: 65% of the patients were male and 35%, female. Patients were divided according to age groups as in the Rockall risk stratification, the score used in this study: two thirds of the patients had 60 or more years and 24% had 80 or more years.

Table 9: Overall results: age groups vs. admission status.

	Total	ED-CHP		Referrals		p
	N (%)	N (%) 8am-8pm	N (%) 8pm-8am	N (%) 8am-8pm	N (%) 8pm-8am	
Age (years)						0.128
<60	214 (33.3)	73 (28.6)	32 (28.3)	23 (41.8)	86 (39.3)	
60-79	274 (42.7)	115 (45.1)	51 (45.1)	23 (41.8)	85 (38.8)	
>80	154 (24.0)	67 (26.3)	30 (26.5)	9 (16.4)	48 (21.9)	
Total	642	255	113	55	219	

As regards the type of admission, 368 (57.3%) were direct admissions to the ED- CHP and 274 (42.7%) were transferred from other hospitals.

The hospitals that most contributed to referrals are illustrated as a Pareto diagram in figure 8.

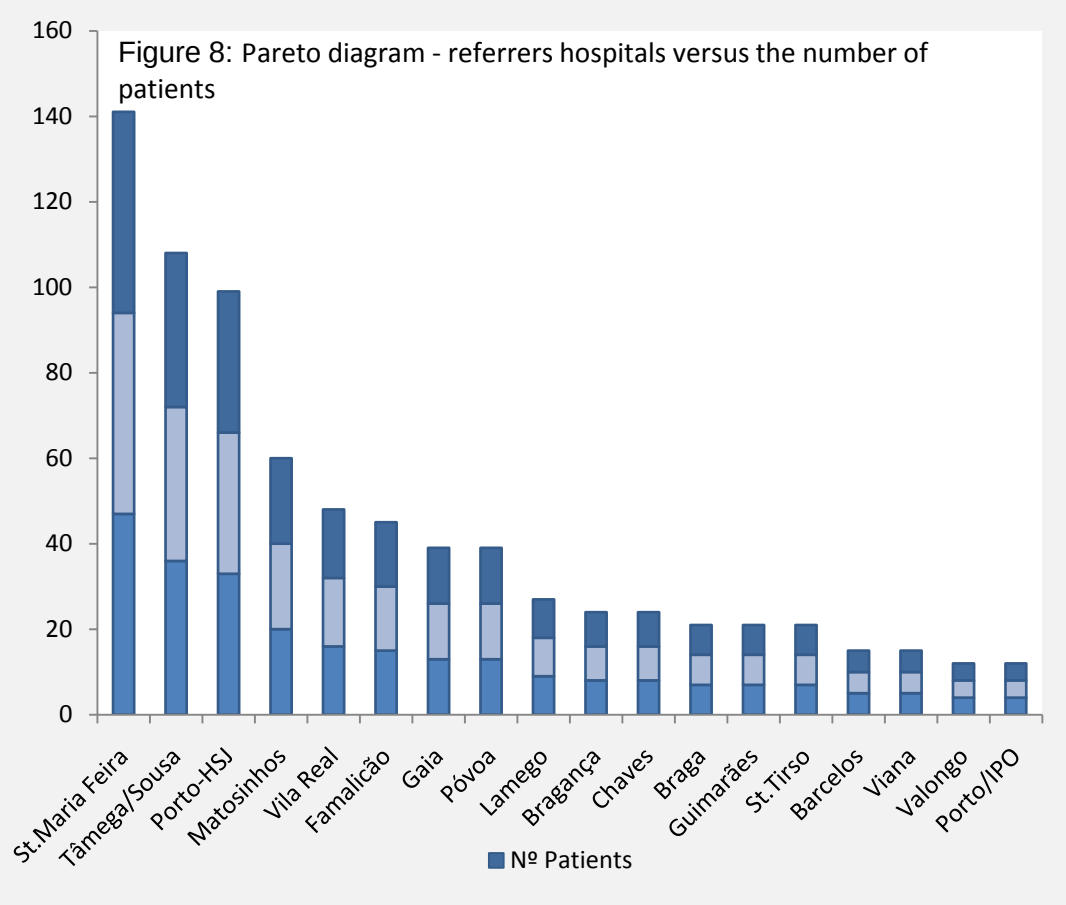
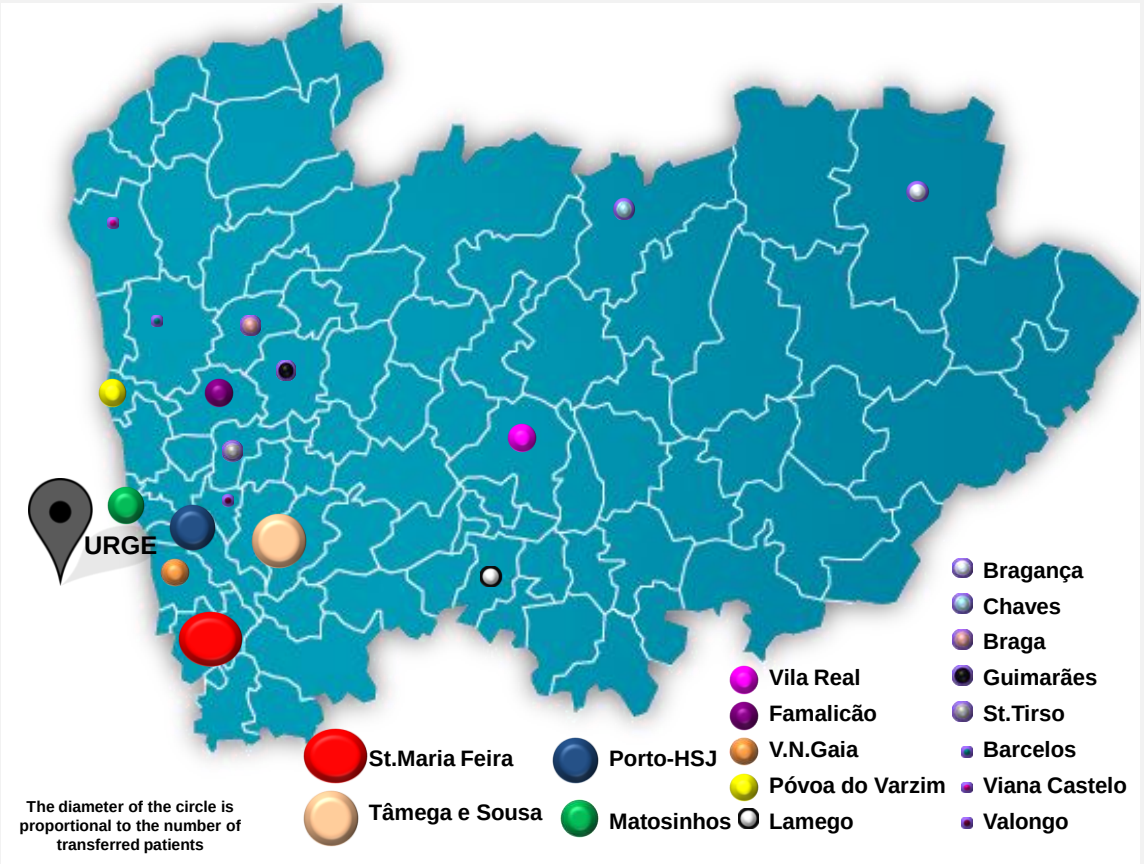


Figure 8: Pareto diagram - referrers hospitals versus the number of patients

It’s worth mentioning that while there were referrals from 30 hospitals, 20% of them were responsible for 65% of the demand, the neighboring institutions. The importance of this flow of patients and hospital's contribution, is geographically demonstrated below in figure 9.

Figure 9: Geographic visualization: flow of patients and hospital's contribution.



The first step in improving the emergency process is to collect the necessary data to understand patient's volume and flow. Timeliness of care can influence the outcome and is an important consideration for patient safety, as well as one of the strongest predictors of patient satisfaction. In order to improve timeliness of care, we must first understand facility-specific utilization and patterns.

Over the three years, the number of cases has decreased, both in local and in transfers, in in-hours and in out-of-hours. Nevertheless, they have remained proportionally distributed over the time periods and months, between the two groups, emergency and transferred (table 10).

Table 10: Overall results - the demand according to the year and month of the year vs. time and admission status.

	Total N (%)	**ED-CHP** N (%) 8am-8pm	N (%) 8pm-8am	**Referrals** N (%) 8am-8pm	N (%) 8pm-8am	**p**
Year						0.097
2010	316 (49.2)	119 (46.7)	48 (42.5)	28 (50.9)	121 (55.3)	
2011	174 (27.1)	70 (27.5)	30 (26.5)	13 (23.6)	61 (27.9)	
2012	152 (23.7)	66 (25.9)	35 (31.0)	14 (25.5)	37 (16.9)	
Total	642	255 (39.7)	113 (17.6)	55 (8.6)	219 (34.1)	
Month						0.187
January	57 (8.9)	22 (8.7)	9 (7.8)	6 (10.9)	20 (9.1)	
February	61 (9.5)	29 (11.4)	8 (7.1)	1 (1.8)	23 (10.5)	
March	68 (10.6)	25 (9.8)	6 (5.3)	7 (12.7)	30 (13.7)	
April	57 (8.9)	20 (7.8)	11 (9.7)	4 (7.3)	22 (10.0)	
May	59 (9.2)	20 (7.8)	11 (9.7)	8 (14.5)	20 (9.1)	
June	64 (10.0)	28 (11.0)	11 (9.7)	6 (10.9)	19 (8.7)	
July	62 (9.7)	21 (8.2)	9 (8.0)	7 (12.7)	25 (11.4)	
August	51 (7.9)	14 (5.5)	17 (15.0)	3 (5.5)	17 (7.8)	
September	44 (6.9)	17(6.7)	12 (10.6)	2 (3.6)	13 (5.9)	
October	39 (6.1)	19 (7.5)	5 (4.4)	5 (9.1)	10 (4.6)	
November	53 (8.3)	29 (11.4)	8 (7.1)	5 (9.1)	11 (5.0)	
December	27 (4.2)	11 (4.3)	6 (5.3)	1 (1.8)	9 (4.1)	

Concerns about determinants of resource demand have been raised and by taking this into account, we also examined changes in productivity in relation to the day of the week and weekday vs. weekend [8pm Friday to 8am Monday].

Direct in-hours admissions were less frequent on Sunday; half of the patients observed on Sunday in-hours, came from other hospitals; by contrast, Sunday and Wednesday nights, were the most busy, at the expense of transferred patients. Two thirds of the patients that were directly admitted in emergency, day or night, did it mostly during the week. On the contrary, patients transferred, day or night, showed a similar distribution, 54.5% and 56.6%, in or out-of-hours, respectively. For NVAUGIB, the less busy day of the week was Thursday (table 11).

When we assayed the service provision by weekday or weekend [from Friday 8pm to Monday 8am] we observe that transferred patients are homogeneous distributed, unlike the patients directly admitted to ED-CHP; this is obviously explained by the lack of provision of endoscopy in many hospitals at weekdays, after 2pm and at weekends. Transferred patients are responsible for 42% and 36% of the endoscopic procedures at weekends and weekdays, respectively.

Table 11: Overall results - the demand according to weekday and weekend vs. time and admission status.

	Total	**ED-CHP**		**Referrals**		**p**
	N (%)	N (%) 8am-8pm	N (%) 8pm-8am	N (%) 8am-8pm	N (%) 8pm-8am	
Day of the week						0,004
Sunday	87 (13.6)	22 (8.6)	10 (8.8)	11 (20.0)	44 (20.1)	
Monday	90 (14.0)	40 (15.7)	16 (14.2)	9 (16.4)	25 (11.4)	
Tuesday	87 (13.6)	36 (14.1)	21 (18.6)	3 (5.5)	27 (12.3)	
Wednesday	103 (16.0)	42 (16.5)	12 (10.6)	7 (12.7)	42 (19.2)	
Thursday	74 (11.5)	35 (13.7)	17 (15.0)	4 (7.3)	18 (8.2)	
Friday	101 (15.7)	46 (18.0)	20 (17.7)	7 (12.7)	28 (12.8)	
Saturday	100 (15.6)	34 (13,3)	17 (15.0)	14 (25.5)	35 (16.0)	
Weekday	430 (67.0)	199 (78.0)	77 (68.1)	30 (54.5)	124 56.6)	0,000
Weekend	212 (33.0)	56 (22.0)	36 (31.9)	25 (45.5)	95 (43.4)	

Patients are stabilized in the nearest hospital and transferred after agreement with the consultant gastroenterologist. This was accomplished in 68% of the cases, according to the standardized questionnaire, filled out by the attending physician or the assistant nurse.

Of the 642 patients, 67% we admitted during the week and 33% during weekend. More patients were admitted after-hours (52%) compared with in-hours (48%).

Procedures performed after-hours were further analyzed and we observed that 54% occurred between 12am and 8am.

The patient flow, lead time was examined as detailed in the next table:

Table 12: Overall results - Patient Flow: Lead Time.

Lead time	**ED-CHP**		**Referrals**		**P**
Median Time (hours)	8am-8pm	8pm-8am	8am-8pm	8pm-8am	
From first ED to ED-CHP			15.0	6.8	0.003
Weekday			16.1	6.5	0.013
Weekend			11.5	7.7	0.302
From first ED to endoscopy	4.32	6.0	14.7	7.7	0.009
Weekday	7.8	8.8	11.5	8.8	0.130
Weekend	7.9	5.4	9.5	8.3	0.178

As noticed in table 12, time to arrival to ED-CHP was significantly higher during the day compared with the night (15h vs. 7h, p=0.003).

Patients transferred during daytime had a significantly longer time to endoscopy compared with patients admitted during the night (15h vs. 7h, p=0.009).

Patients were predominantly men (67%) with 24% of them with 80 years old or more and similar between groups. The characteristics of the patients are outlined in table 12, according to time and status of admission. Patients' age are not significantly different among the four groups. Patients admitted out-of-hours presented more often with haematemesis (72% and 74% vs. 45% and 56% respectively, p<0.000). Comorbidities were not significantly different among the four groups, but patients admitted to ED-CHP,

during the day, tended to be more often known with metastatic malignancy and vascular disease (p=0.05 and p<0.05). Patients characteristics are detailed in table 13.

Table 13: Overall results - Patients characteristics for NVAUGIB and in sub-groups according to time and admission status.

	Total	**ED-CHP**		**Referrals**		**p**
	N (%)	N (%) 8am-8pm	N (%) 8pm-8am	N (%) 8am-8pm	N (%) 8pm-8am	
Sex						0.527
Male	430 (67)	166 (65)	74 (66)	20 (36)	64 (29)	
Female	212 (33)	89 (35)	39 (34)	35 (64)	155 (71)	
Age (years)						0.128
< 60	214 (33.3)	73 (28.6)	32 (28.3)	23 (41.8)	86 (39.3)	
>60 - <80	274 (42.7)	115 (45.1)	51 (45.1)	23 (41.8)	85 (38.8)	
≥80	154 (24.0)	67 (26.3)	30 (26.5)	9 (16.4)	48 (21.9)	
Clinical presentation						
Hematemesis	374 (58.9)	116 (45.7)	73 (74.6)	31 (56.4)	154 (72.3)	0.000
Melena	320 (50.4)	133 (52.4)	46 (40.7)	36 (65.5)	105 (49.3)	0.021
Hematochezia	41 (6.5)	13 (5.1)	9 (8.0)	4 (7.3)	15 (7.0)	0.715
Comorbidities (N=638)						
Cardiac disease	84 (32.9)	38 (33,6)	13 (23.6)	38 (33.6)	55 (25.6)	0.185
Chronic renal disease	70 (11.0)	35 (13,7)	15 (13.3)	5 (9.1)	15 (7.0)	0.098
Blood disorders	11 (1.7)	3 (1,2)	5 (4.4)	2 (3.6)	1 (0.5)	0.037
Chronic liver disease	78 (12.2)	30 (11,8)	16 (14.2)	10 (18.2)	16 (14.2)	0.383
Vascular disease	63 (9.9)	37 (14,5)	12 (10.6)	3 (5.5)	11 (5.1)	0.005
Previous stroke	63 (9.9)	27 (10,6)	9 (8.0)	2 (3.6)	25 (11.6)	0.289
Peptic ulcer disease	84 (13.2)	32 (12,5)	22 (19.5)	3 (5.5)	27 (12.6)	0.074

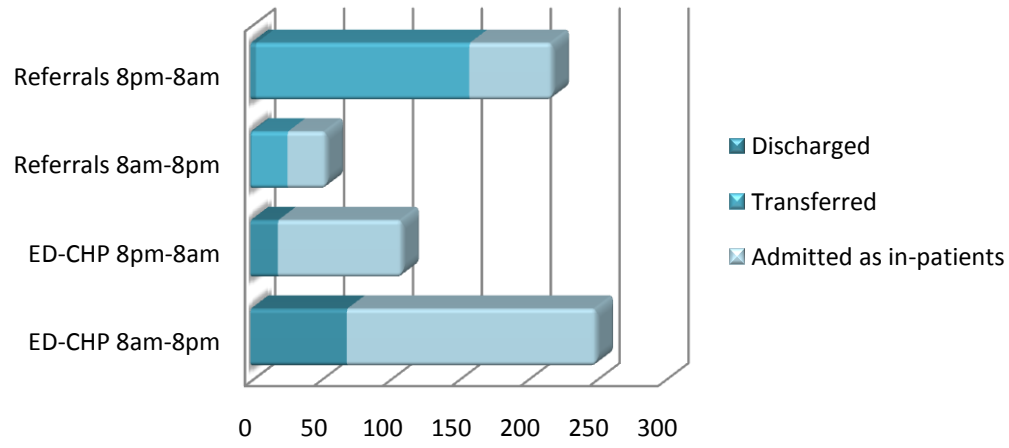
complicated or not						
Hypertension	291 (45.6)	125 (49.0)	43 (38.1)	27 (49.1)	96 (44.7)	0.246
Diabetes	149 (23.4)	68 (26.7)	26 (23.0)	9 (16.4)	46 (21.4)	0.317
Malignancy	81 (12.7)	41 (16.1)	16 (14.2)	6 (10.9)	16 (14.2)	0.084
Metastatic malignancy	20 (3.1)	14 (5.5)	2 (1.8)	1 (1.8)	3 (1.4)	0.050
Renal or liver Transplanted	11 (1.7)	8 (3.1)	2 (1.8)	1 (1.8)	0 (0.0)	0.079
Nº of comorbidities						
None	130 (20.4)	41 (16.1)	25 (22.1)	14 (25.5)	50 (23.3)	0.012
1	177 (27.7)	63 (24.7)	29 (25.7)	19 (34.5)	66 (30.7)	
2	154 (24.1)	65 (25.5)	21 (18.6)	10 (18.2)	58 (27.0)	
≥ 3	177 (27.7)	86 (33.7)	38 (33.6)	12 (21.8)	41 (19.1)	
Medication	350 (55.2)	139 (54.7)	53 (53.1)	31 (56.4)	120 (56.6)	0.342
Anticoagulation at presentation	73 (11.4)	34 (13.3)	11 (9.7)	3 (3.6)	26 (11.9)	0.204
Aspirin intake						
AAS 100	95 (15.1)	39 (15.4)	18 (15.9)	5 (9.6)	33 (15.6)	0.718
AAS 150	95 (15.1)	35 (13.8)	10 (8.8)	7 (13.5)	25 (11.8)	0.591
Clopidogrel	77 (12.2)	26 (10.2)	18 (15.9)	2 (3.7)	19 (9.0)	0.077
NSAID use	129 (20.4)	49 (19.3)	19 (16.8)	15 (28.3)	46 (21.7)	0.342
Anticoagulation + Aspirin + clopidogrel	6 (0.9)	4 (1.6)	1 (0.9)	0 (0.0)	1 (0.5)	0.538
Aspirin + Clopidogrel	30 (4.7)	11 (4.3)	8 (7.1)	0 (0.0)	8 (7.1)	0.231
PPI before endoscopy N=602	467 (77.6)	186 (75.6)	89 (79.5)	37 (75.5)	155 (79,5)	0.728
Clinical Rockall score						0.150

Low risk ≤ 2	283 (44.7)	105 (41.2)	50 (44.2)	29 (53.7)	99 (46.9)	
Moderate risk 3-4	254 (40.1)	113 (44.3)	39 (34.5)	16 (29.6)	86 (40.8)	
High risk >4	96 (15.2)	37 (14.5)	24 (21.2)	9 (16.7)	26 (12.3)	
Low risk ≤ 2	283 (44.7)	105 (41.2)	50 (44.2)	29 (53.7)	99 (46.9)	0.323
Moderate / High risk ≥3	350 (55.3)	150 (58.8)	63 (55.8)	25 (46.3)	112 (53.1)	
Complete Rockall score (N=627)						0.115
Low risk ≤ 2	71 (11.3)	35 (13.8)	7(6.2)	7 (13.2)	22 (10.6)	
Moderate risk 3-4	192 (30.6)	73 (28.7)	28 (25.0)	19 (35.8)	72(34.6)	
High risk >4	364 (58.1)	146 (57.5)	77 (68.8)	27 (50.9)	114 (54.8)	
Low risk ≤ 2	71 (11.3)	35 (13.8)	7(6.2)	7(13.2)	22(10.6)	0.195
Moderate /High risk ≥3	556 (88.7)	219 (86.2)	105 (93.8)	46(86.8)	186 (89.4)	
Hemodynamics						
Stable	350 (56.7)	155 (62.2)	63 (55.8)	31 (57.4)	101 (50.2)	0.103
Heart rate > 100 beats/min	138 (22.4)	49 (19.7)	21 (18.6)	15 (27.8)	53 (26.4)	0.103
Systolic blood pressure < 100mmHg	129 (20.9)	45 (18.1)	29 (25.7)	8 (14.9)	47 (23.4)	0.103
Systolic blood pressure ±SD, mmHg	120±25	122±25	116±24	125±27	118±24	0,024
Diastolic blood pressure ±SD, mmHg	66±14	67±14	62±14	67±15	65±14	0.021

Heart rate ±SD beats/min	92±20	88±19	91±23	94±23	92±20	0.001
Hemoglobin ±SD g/dL	9,0±3,8	8,7±2,8	9,1±2,7	8,7±2,6	9,4±5,3	0.199
Hemoglobin ≤ 7 g/dL	175 (27.9)	75 (29.5)	29 (25.7)	22 (42.3)	49 (27.9)	0.047
Hemoglobin > 7 g/dL	452 (72.1)	179 (70.5)	84 (74.3)	30 (57.7)	159 (76.4)	0.047

EGD was performed in all patients, and 16.8% had to repeat the procedure, because of some limitations, namely blood, food or patient's intolerance, without sedation. The probability of repeating EGD was significantly higher in patients directly admitted to ED-CHP. Just 6.8% of the patients were admitted in intensive care units; 15% were discharged and 56% were admitted as inpatients in CHP (figure 10).

Figure 10: Planning after EGD



The first EGD was performed within 24h of presentation in 86% of the patients. Of the 642, 290 (45%) required endoscopic therapy for hemostasis. Peptic ulcer was the main diagnosis (51%) being 52% gastric and 48% duodenal ulcers. Rebleeding was reported in 8.9% and the 30-day mortality in this case cohort was 7.5% (46/615), being the bleeding episode responsible for 30% of the deaths. Significantly more patients endoscoped during

the night had surgery (p=0.015). The other outcomes were independent of the time or status of admission.

Table 14: Overall results - Patients outcomes for NVAUGIB and in sub-groups according to time and admission status.

	Total	**ED-CHP**		**Referrals**		**p**
	(%)	(%) 8am-8pm	(%) 8pm-8am	(%) 8am-8pm	(%) 8pm-8am	
Rebleeding	8.9	8.3	11.6	6.4	8.7	0.687
Surgery	4.1	1.6	8.0	1.9	5.8	0.015
In- hospital mortality	6	6	6	7	5.1	0.326
30 day mortality	7.5	7.1	8.9	10	6.5	0.774

No adverse events were reported during transfer but during the procedure: one sentinel event (death after cardio respiratory arrest) and four severe (one perforation after therapeutic endoscopy and three aspiration pneumonias); transient tachycardia, hypoxemia or self-limited bleeding were recorded as minor incidents.

The median length of hospital stay was 6 days for both admission status groups.

CHAPTER IV
RESULTS

IVa. Overall Results

IVb. Main Results

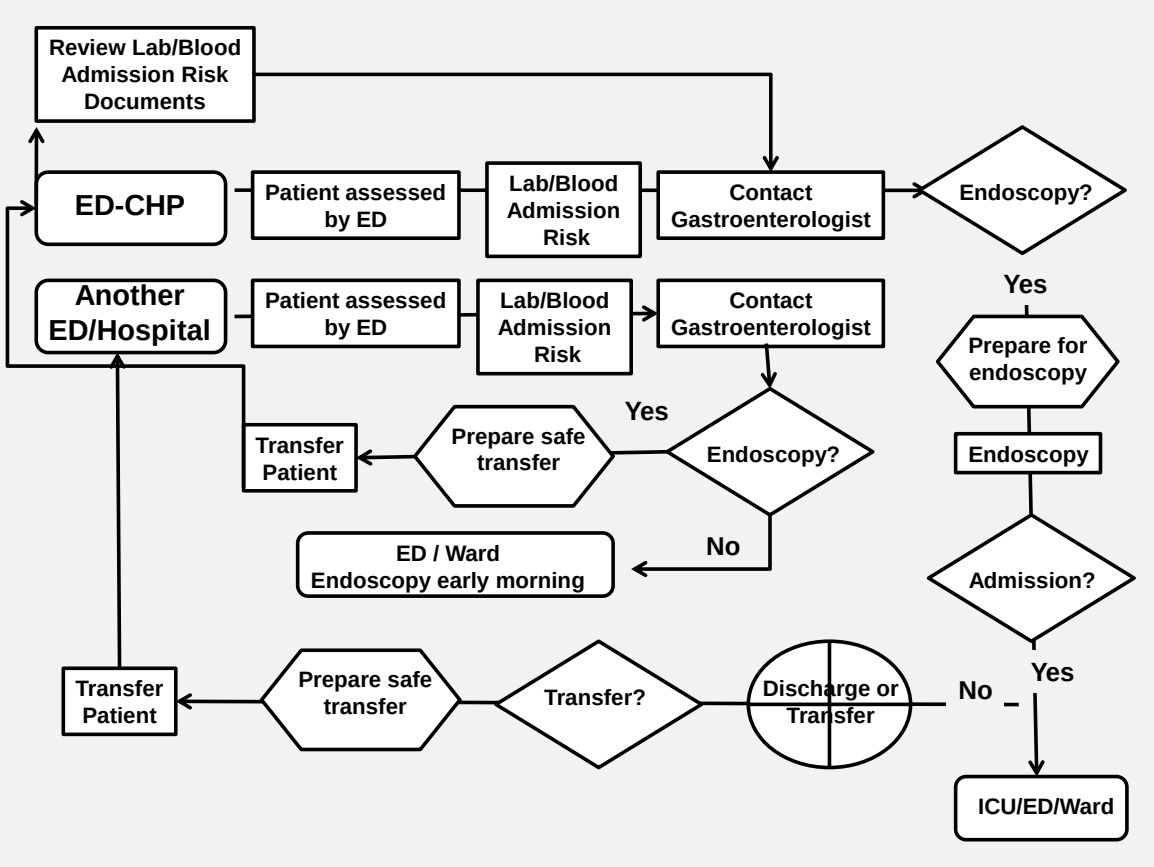
IV. RESULTS

IVb. Main Results

The main results of this study are in the third paper that assesses the organization model of out-of-hours endoscopy by comparing two groups of patients, transferred vs. non-transferred.

The paper reinforces that NVAUGIB management requires the coordination of physicians, non-physician staff, rooms and equipment and can be described as a multi-step process for transferred patients: (1) admission to first ED; (2) clinical assessment and stabilization; (3) contact with the gastroenterologist of ED-CHP; (4) transfer; (5) admission to ED-CHP; (6) revision of patient's clinical condition; (7) endoscopic procedure; (8) planning after endoscopy; (9) transfer; (10) post-endoscopy management (figure 11).

Figure 11: Patient workflow described as a multi-step process: visualizing the patient's journey.



Paper III

Out-of-Hours Endoscopy for Non-Variceal Upper Gastrointestinal Bleeding

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Out-of-Hours Endoscopy for Non-Variceal Upper Gastrointestinal Bleeding

Background: Most countries lack a well-coordinated approach to out-of-hours endoscopy. Economic constraints and lack of resources have been identified as important barriers.

Objective: To assess the performance evaluation of an out-of-hours emergency endoscopy model of care.

Design: During a 3 year period (January 2010 to December 2012), data from consecutive outpatients (n=332) with non-variceal acute upper gastrointestinal bleeding (NVAUGIB) admitted or transferred to a single referral hospital were prospectively collected.

Results: 34 % (n=113) were direct admissions whereas 66% (n=219) were transferred from other hospitals. Median time to upper endoscopy (EGD) was 6h and 7.7h for direct admissions and transferred respectively. EGD was performed within 24h in 90% of the patients. Rebleeding, in-hospital mortality, 30 day mortality and need for surgery were respectively 9.8%, 5.8%, 7.4% and 6.6% and were not significantly different between the two groups. Age, malignancy and moderate to high clinical Rockall risk score were independent predictors of in-hospital mortality in both groups. Age remained as an important predictor of main outcomes in transferred patients, while comorbidities differed according to admission status and predictable outcomes.

Conclusions: This gastroenterology emergency model improved access and equity to out-of-hours endoscopy in an effective, safety and timely way, recognized by the rates and the homogeneity observed in the outcomes, between transferred patients and direct admissions.

Keywords: Clinical-effectiveness; emergency care; non-variceal upper gastrointestinal bleeding; out-of-hours endoscopy; services provision.

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Introduction: Acute upper gastrointestinal bleeding (AUGIB) is the commonest cause of acute hospital admission to gastroenterology and therefore has a large impact on the acute medical admission workload. Changes in management have been shown in randomized controlled trials to improve outcome from AUGIB, but large observational studies of mortality trends following upper gastrointestinal hemorrhage reported no improvement in overall mortality over the last 2 decades (Rockall, Logan et al. 1995; van Leerdam, Vreeburg et al. 2003). The mortality associated to non-variceal acute upper gastrointestinal bleeding (NVAUGIB) remains significant, despite the therapeutic advances (Lanas, Perez-Aisa et al. 2005; Leontiadis, Sharma et al. 2005; Lanas, Garcia-Rodriguez et al. 2009; Sung, Barkun et al. 2009; Sung, Tsoi et al. 2010). It is important to notice that differences in practice may be hampering comparisons between countries. Even in the same country, variability in patient's management is observed (Hearnshaw, Logan et al. 2010; Muthiah, Enns et al. 2012). In this respect, NVAUGIB despite being an important reason for acute admission, the outcomes of patients who have experienced a NVAUGIB are poorly understood as a function of the all process of care (Pedroto, Amaro et al. 2013). Regionalization improves patient outcomes through two primary mechanisms: improved outcomes at high-volume, high-specialty centers, and improved coordination of care within a given geographic area. The latter was the model adopted in northern Portugal. In October 2006, a regional emergency endoscopic out-of-hours center with different specialists from 8 public institutions, at the same physical location, in the out-of-hours period, was set up. We thought that this model might offer high availability and quality at every stage, as well as continuity between each step of an interconnected treatment process, that would reduce the patient’s waiting time for endoscopy, speed up

recovery with a multi-disciplinary approach, and manage resources in a more efficient way. Therefore we aimed at assessing the model performance by getting better insight into its effect on outcomes.

Methods

Patients selection: Data on all consecutive patients, aged 18 and over, admitted directly to the emergency department of Centro Hospitalar do Porto (ED-CHP) or transferred from another institution, were prospectively collected. As we have decided, at this stage, to focus on specific causes of bleeding so that current management strategies and prognosis could be put into adequate context, only patients who performed an upper endoscopy confirming a new onset of NVAUGIB (clinical evidence of overt upper bleeding on admission or a history of hematemesis, coffee ground vomiting, melena, hematochezia, or a combination of any of these within 24h preceding admission) were included. Patients were also excluded if they were younger than 18 years old, if endoscopy was not performed, had chronic anemia or bled as inpatients hospitalized for an unrelated illness. Demographic, clinical and endoscopic data from patients with NVAUGIB were collected. Comorbidity was defined as the presence of any of the following diseases: (1) cardiac disease including ischemic heart disease and congestive heart failure; (2) hypertension; (3) chronic liver disease; (4) chronic renal disease; (5) vascular disorders including peripheral and central vascular diseases; (6) history of stroke; (7) diabetes; (8) malignancy; (9) metastatic malignancy; (10) renal or liver transplant; (11) hereditary bleeding disorder; (12) peptic ulcer disease, complicated or not. All medication, at time of presentation, was recorded. Patient workflow was examined: time of admission at the first hospital, time of first

contact to the endoscopy unit, time of arrival to the endoscopy unit, time of endoscopic procedure, time of inpatient admission, discharge or transferred back to the first hospital; endoscopic lesion and therapy; adverse events. Mortality was defined as any death occurring during hospitalization or within 30 days of the index bleeding episode and considered as bleeding related (after uncontrolled bleeding; occurring within 24h after endoscopy; during surgery for uncontrolled bleeding; adverse events during endoscopy or surgery) or non-bleeding related (comorbidity or nosocomial infections). Rebleeding was defined as recurrent haematemesis, melena, with hemodynamic instability or a decrease in hemoglobin concentration of at least 2g/L and confirmed by a second endoscopy, recurring within 30 days.

Model of Care

Site, staff and capacity: From January 2010 to December 2012, a prospective observational study was conducted at the endoscopy unit of CHP, a 820-bed acute care teaching hospital serving, as an out-of-hours endoscopy center, an estimated population of 3.7 million (one third of the national population), with about 38 percent of the national youth population concentrated in the region. The northern region includes eight sub-regions and an area of about 21.278 km² (24% of the continent). Since October 2006, in CHP, 30 consultant trained gastroenterologists from eight hospitals and sixteen skilled assistant staff from the endoscopy unit (eight nurses and eight endoscopy technicians) were integrated as the emergency team, everyday from 8 pm to 8 am; they are responsible for handling all gastroenterology emergencies, especially those requiring urgent endoscopy. The objectives of the Urgência Regional de Gastroenterologia (URGE) are: to provide phone consultations during the night; to provide consultations on

site and endoscopy. URGE receives around 800-1000 patients/year, being around 53% of the patients acute upper bleeders; a non-variceal cause accounts for approximately 52% of these. Each institution is accountable for the remuneration for out-of-hours gastroenterology physician work, except for the assistant staff (nurse and endoscopy technician) that is the sole responsibility of the endoscopy unit of CHP. In this way, all are allocating human and financial resources. CHP has eight emergency teams and quarterly, the head of the gastroenterology department from five hospitals, is responsible for sending to the URGE coordinator the physicians rota, according to the teams which have been assigned to them; physicians from the smaller units strengthen some teams; this reflects 1 shift/physician/month. The provision of emergency endoscopy fulfills all the recommendations of the British Society of Gastroenterology**.** CHP has elective beds for bleeders in the acute medical or surgery units and two intensive care units.

The Process: After the patient's arrival at the emergency department (ED), they are taken care of firstly by ED staff; after the first-steps in the patient's care, the gastroenterologist is called and the emergency GI upper endoscopy (EGD) is performed by the gastroenterology staff. Referral patients are stabilized in the nearest hospital and transferred after agreement with the consultant gastroenterologist. When appropriate and safe, the procedure takes place in the endoscopy unit or in the emergency room or theatre. The decision to, where and when to perform EGD, diagnostic or therapeutic, is decided by the individual endoscopist, although he is guided by a regional protocol, which defines the need for therapeutic endoscopy according to international consensus

statements(Barkun, Bardou et al. 2010; Laine and Jensen 2012). The endoscopist determines the level of anesthetic support. After the procedure, the patients are admitted or transferred back to their institution. Our practice is to perform EGD before discharge on all patients who have AUGIB and then, decide to, admit, discharge or transfer. In order to identify whether interventions might improve quality of care, the authors prospectively collected data, to investigate the outcomes of these patients and correlate them to the all process of care. We took several important steps: the first retrospective clinical audit, twelve months after the model's implementation, demonstrated weak adherence to important aspects of care and highlighted the areas that required improvement. In 2010, clinical guidelines, including safe transfer practice, for AUGIB were implemented and spread among all the northern institutions, whatever their level of care. They were reviewed and approved by the directors of all gastroenterology departments and published (I Pedroto and F Magro. Gestão Clínica da Hemorragia Digestiva Alta: Normas de Orientação Clínica. Conselho Diretivo da ARS-Norte, 2010). Also, check sheets have been updated; the pilot test showed that the first was too long, with a large number of items; now a simple check sheet, that separates the process into sub steps, is fulfilled for all the bleeding patients: time of contact, time of arrival, hemodynamics, risk stratification, medication, time of endoscopy, time of discharge; nurses do part of this job. Data are filled out by the attending physician. The URGES' coordinator is responsible for checking the standardized-item list. The complete 30 days follow-up was ensured by analysis of the electronic database or by direct telephone contact.

Outcomes: The main outcomes and quality measures were: time to endoscopy, rebleeding, surgical intervention and mortality, length of hospital stay, safety,

timeliness, equity and efficiency. Our primary variables was the admission status, direct admission to ED-CHP or transferred from another institution.

Statistical analysis: Categorical variables were described as absolute frequencies (n) and relative frequencies (%). Median and percentiles or median and standard deviation were used for continuous variables. When testing a hypothesis about categorical variables a chi-square test and Fisher's exact test were used, as appropriate. In order to have a more thorough understanding of the factors associated, with mortality (in-hospital and 30 day) and rebleeding, univariate and multivariate logistic regression modeling was used. Factors that were significant in the univariate analysis at $p<0.2$ were included in the multivariate logistic regression models. Variables that have been previously identified to carry important prognostic significance in patients with NVAUGIB were included in the final multivariate model even if they didn't meet statistical significance on univariate analysis. Model discriminative power was evaluated by receiver-operator curve (ROC) curve analysis with confidence interval 95% (CI95%). The significance level used was 0.05. Statistical analysis was performed using the software Statistical Package for the Social Sciences v. 20.0.

Ethics approval

The study was approved by the Ethics Committee of Centro Hospitalar do Porto. Patient consent was obtained according to local regulations.

Results:

The patients: between January-2010 and December-2012, all consecutive patients who had an out-of-hours endoscopic diagnosis of NVAUGIB were identified. We enrolled 332 patients with a mean age of 65±16 years (23-97) with a significantly higher proportion of men (69% vs. 31%); about two thirds of the patients had 60 or more years and 27% had 80 or more years. There were no differences in hemodynamics at presentation in first ED admission, nor in laboratory test results (such as hemoglobin). The admission Rockall risk score identified 44% and 47% as low-risk patients and the remaining 56% and 53% as moderate to high risk. The complete score categorized 9%, 31% and 60% of the patients as low, moderate and high risk respectively. The detailed patients characteristics are shown in table 1.

The process: as regards the type of admission, 113 (34%) were admissions to the ED-CHP and 219 (66%) were transferred from other hospitals. It's worth mentioning that while there were referrals from 30 hospitals, 20% of them were responsible for 65% of the demand, the neighboring institutions. Median time from admission to first hospital and arrival to CHP was 6.8h. The patient flow, lead-time, is illustrated in table 2. EGD had no limitations in 60.5% of the cases. The global major endoscopic findings were: peptic ulcer 56% (55% gastric ulcers; 45% of admissions and 62% of referrals) 88% with stigmata of active or recent bleeding defined according to the Forrest classification (FIa 7%, FIb 15%, FIIa 35%, FIIb 18%, FIIc 25%); Mallory-Weiss tear 14.8%, erosions 5.7%, esophagitis 4.5%, tumor 4.2%, arteriovenous malformations and bleeding after endoscopic therapy (resection techniques) 3.9%; not determined in 1.5% of EGDs. Endoscopic therapy was performed in 56% of the patients and was combined in 77% of the

cases: injection and mechanical therapy (clips) 42%, injection 39% and injection and thermal therapy in 19%.

The outcomes: EGD was performed within 24h in 90% of the patients and in less than 6h in 40% of these. The median number of units of blood transfused was two. Surgery was carry out in those patients whose bleeding could not be stopped by primary endoscopic hemostasis or by a second endoscopic therapy, in 6.5% of the patients. No adverse events were reported during transfer but two during endoscopy, namely, aspiration pneumonia and respiratory arrest; transient tachycardia, hypoxemia or self-limited bleeding were recorded as minor incidents in 4 patients. Rebleeding occurred in 29 patients (29/295; 9.8%): 11.6% in direct admissions and 8.7% in transferred patients (p=0.423). In-hospital mortality was 5.8% (18/311): 7.1% vs. 5.1% in direct admissions vs. referral patients (p=0.461). Thirty day mortality was also not significantly different between the two groups, 7.4% (23/311), 8.9% for direct admissions and 6.5% for transferred patients (table 3). Ongoing bleeding and rebleeding were the cause of death in 30% of the cases (20% in ED-CHP and 38% in transferred). The remaining 70% died from comorbidities and nosocomial infections. The median length of hospital stay was 6 days for both groups (0-61 and 0-72 days for direct admissions vs. transfers). After EGD, 20% and 80% of the patients admitted directly to ED-CHP were discharged or admitted as inpatients; 71% of the referrals were transferred back to their first admission hospital and 27% stayed in CHP' units or ward, while 4% were discharged.

After multivariate analysis only a few variables remained important in the prediction of rebleeding or mortality. The majority of rebleeding patients directly admitted to ED-CHP had a history of previous ulcer disease and a longer

timeframe to endoscopy (AUC=0.652 [0.476-0.829]). In the transferred group, patients with 80 years old or more showed a 11-fold significantly increased risk of rebleeding, than younger patients (AUC=0.753 [0.632-0.875]). Patients transferred with malignancy, a high risk clinical Rockall score and more than 80 years old presented a probability of 30-day mortality, three, six and sixteen times greater (AUC=0.863 [0.775-0.951]).

Discussion

Despite the advent of endoscopic therapy, the accessibility of the patients to medical centers with experienced medical staff and adequate equipment is still limited in out-of-hours. The first step in improving the emergency process is to collect the necessary data to understand patient's volume, flow and outcomes. Timeliness of care can influence the outcome and is an important consideration for patient safety, as well as one of the strongest predictors of patient satisfaction. In order to improve timeliness of care, we must first understand facility-specific utilization and patterns. Comparisons of the present study with previous ones is difficult by the type of the population analyzed, direct admissions versus referrals from other institutions, once work in this area is scarce.

Several implications can be drawn from this study:

First, the organizational model**:** in this paper we present the results of NVAUGIB but many other emergencies need gastroenterological attention and all of them, and all patients (regardless of their geographical location) deserve a safe and effective care. The urgent gastroenterology service must not be addressed differently from others, like cardiology, pediatrics or trauma. Some reports have looked into some feasible options of emergency services configuration and others

have identified serious gaps in out-of-hours emergency endoscopy services (Hearnshaw, Logan et al. 2010). Our model has led to several benefits: first, an equal emphasis was placed on all patients from the northern region in terms of structure and process. Second, the participation of only consultant gastroenterologists, an experienced endoscopist nurse and an endoscopy technician that cleans and reprocesses the endoscopes, ensures safer care (Douglass, Bramble et al. 2005; da Silveira, Lam et al. 2006; Gibson, Hitchcock et al. 2006; Gyawali, Suri et al. 2007; Barkun 2010; Francisco José Martinez Cerezo 2011; Heymann 2011; Jairath, Kahan et al. 2012; Muthiah, Enns et al. 2012; Cesaro, Kohn et al. 2013). Third, this model has led to a concentration of specialized work in a large hospital without compromising the emergency workload nor the physicians workday planning in their institutions; it must be understood as a fair distribution of duties instead of a duplicity of faint care in all or some hospitals. The increase in hours of activity is equitably distributed by the eight institutions, from Oporto district and one from Aveiro's district. Fourth, to avoid the ED-CHP overcrowding, transferred patients that don't require resuscitation or stabilization (most of them) by-pass the emergency department and go directly to the endoscopy unit; on the other side, by having staff with the right skill, in the right place at the right time, the planning decision is taken in a timely manner for the patient after endoscopy. And in fact, 71% of the referrals were transferred back to the admission hospital, without creating greater demand bed (20 patients/year) nor theater constraints (4 patients/year); and 23% of direct admissions to ED-CHP were early discharged. Fifth, there was management widespread support for the new organization, with clinical guidelines disseminated and implemented appropriately as observed by clinical risk stratification in 98% of the patients, and

medication and comorbidities highlighted. These items are consistent with the study from Silveira and col., that emphasized the importance of the process of care (da Silveira, Lam et al. 2006). Sixth, although economic costs associated with admissions for patients with NVAUGIB are not available in Portugal, we can probably assume potential savings in hospitals where endoscopy is only available from Monday to 2pm Friday and in those with difficulties in endoscopy arrangements, even on weekdays. Our next step is to know our costs by mapping the patient's journey: ED admission; transfer; endoscopy session; costs/bed/day. However, the recent guidelines published by the National Institute of Clinical Excellence reported that units with more than 330 presentations of AUGIB per year are cost effective with an everyday service (2012); they didn't take into account the weekend, with probably more income, which is our case. So in our model, we have the structure, the volume and the process in place. In the near future, a cost effective analysis will be presented.

Second, the relationship between service provision and outcomes. Our dependent variable was type of admission, direct admissions to ED-CHP vs. transferred patients. There was considerable homogeneity between groups: age, comorbidities, medication intake, risk stratification, baseline haemoglobin and hemodynamic at presentation. This translated to similar rates of outcomes which are consistent (Blatchford, Davidson et al. 1997; Hershcovici, Haklai et al. 2010) and even better (Rockall, Logan et al. 1995; van Leerdam, Vreeburg et al. 2003; Loperfido, Baldo et al. 2009) than previous published population based studies. Moreover, the cause of bleeding was peptic ulcer in 56% of the cases, a rate slightly higher than in other published studies (Zimmerman, Meroz et al. 1994; Lanas, Aabakken et al. 2011; Villanueva, Colomo et al. 2013). So, by examining

the impact of out-of-hours endoscopy in patients with NVAUGIB we demonstrated the following: (1) 90% of the patients had an endoscopy performed in less than 24h; (2) The transferred patients had a similar timeframe to endoscopy when compared to direct admissions; (3) The rates of rebleeding, in-hospital mortality and 30 day mortality were not significantly different according to the admission status; (4) Transferred patients with 80 or more years old were more likely to rebleed; (5) Clinical Rockall risk score predicted 30 day mortality in transferred patients unlike direct admissions where malignancy was the only strongest parameter; this may be particularly important in the decision to transfer, without delays; (6) The median length of hospital stay was 6 days for both groups, considered to be reasonable given the 60% of high risk patients and patient's age and comorbidities; (7) 71% of the referrals were transferred back, after endoscopy, to the first admission hospital; (8) we can always discuss whether we have done our part and whether it was enough. This relates mainly to post-endoscopic management, also a component of the all process of care.

A strength of our study is that it demonstrates how a simple and safe model of care allows all NVAUGIB patients requiring urgent gastroenterologist care, regardless of where they live, to be cared for in the most appropriate setting in a timely and efficient manner. A limitation of our study is that it was not possible to determine the impact of the regionalization model on the economics of the hospitals that integrate the model, a work to be done in the near future. It also was not possible to determine this model cost-benefit and relative to other management strategies due to limited data avalailable on costs and efficacy. In this model, the importance of joining forces is undoubtedly demonstrated, has

already brought results, and enables available resources to be equitably distributed and accessible to the entire population of northern Portugal.

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Tables and table legends

Table 1

Clinical and laboratory features of the study population according to admission status

	Total N=332	ED-CHP (N=113) (%)	Transferred (N=219) (%)
Male Gender	229	66	71
Age (years)			
< 60	118	28	39
>60 - <80	136	45	39
≥80	78	27	22
Clinical presentation			
Hematemesis	227	75	72
Melena	151	41	49
Hematochezia	24	8	7
Comorbidities			
Cardiac disease	68	24	26
Chronic renal disease	30	13	7
Blood disorders	6	4	0,5
Chronic liver disease	32	14	14
Vascular disease	23	11	5
Previous stroke	34	8	12
Peptic ulcer disease	49	20	13
Hypertension	139	38	45
Diabetes	72	23	21
Malignancy	32	14	14
Metastatic malignancy	5	2	4
Renal or liver transplanted	2	2	0

Number of comorbidities			
None	75	22	23
1	95	26	31
2	79	19	27
≥ 3	79	34	19
Medication			
With medication	145	47	43
Anticoagulation at presentation	37	10	12
Aspirin intake			
AAS 100	95	16	15
AAS 150	51	16	16
Clopidogrel	35	9	12
Aspirin + Clopidogrel	37	16	9
Anticoagulation + Aspirin +	16	7	7
Clopidogrel	2	1	1
NSAIDs use	65	17	22
PPI before endoscopy	244	80	80
Clinical Rockall score at first			
ED admission			
Low risk ≤ 2	149	44	47
Moderate risk 3-4	125	35	41
High risk >4	50	21	12
Missing	8		
Complete Rockall score			
Low risk ≤ 2	30	6	11
Moderate risk 3-4	101	25	35
High risk >4	194	69	55

Missing	11		
Hemodynamic at presentation (first ED admission)			
Normal	164	56	50
Heart rate > 100 beats/min	74	19	26
Systolic blood pressure < 100mmHg	76	26	24
Systolic blood pressure ±SD, mmHg	332	116±24	118±24
Diastolic blood pressure ±SD, mmHg	332	62±14	65±14
Heart rate ±SD beats/min	332	91±23	92±20
Hemoglobin ±SD g/dl	332	9.1±2.7	9.4±5.3

SD, Standard deviation; NSAIDs, no steroidal anti-inflammatory drugs; PPI, proton pump inhibitors

Table 2

Patient flow: Time to admission and time to endoscopy among patients directly admitted to CHP and those transferred

	ED-CHP	Transferred
Median time of admission from first hospital to ED-CHP (hours)		6.8
Weekday		6.5
Weekend		7.7
Median time of admission from first ED to first endoscopy (hours)	6.0	7.7
Weekday	4.7	7.2
Weekend	5.4	8.3
Time to endoscopy as admission from first ED to first endoscopy (%)		
≤6h	46	38
>6h	54	62
≤24h	88	91
>24h	12	9

Table 3

Main Outcomes according to admission status

	ED-CHP (%)	Transferred (%)	Total (%)	p
Rebleeding	11.6	8.7	9.8	0.423
In-hospital mortality	7	5	5.8	0.461
30 day mortality	8.9	4.2	7.4	0.438
Surgery	7.9	5.8	6.5	0.454
Median transfusion requirement (number of units)	2 (0-15)	2 (0-10)	2 (0-15)	0.501

CHAPTER V
DISCUSSION

V. DISCUSSION

This chapter starts with a discussion of the new organization regional model of care. A discussion on the implications for quality of care and the limitations follows.

Paper III provides answers to the research questions about service performance. Structure and staff are an important requirement for being able to predict a safe and effective procedure because NVAUGIB is much more than an endoscopy. And outcomes are much more than numbers or rates. Donabedian (see chapter II) clarified that these categories should not be mistaken for attributes of quality, but rather they are the classifications for the types of information that can be obtained in order to infer whether the quality of care is poor, fair, or good. Outcomes are the result of the patient's interaction with the delivery health care system.

Theorically, what are the strengths, weaknesses and pitfalls of our model of care?

Strengths

Regionalization of health care is a method of providing high-quality, cost-efficient health care to the largest number of patients. It implies the development of a structured system of care by directing patients to the right facilities and expertise. According to Menke TJ and Wray NP, the development of a regionalized system is typically driven by economic factors, such as the infeasibility of all hospitals to maintain the equipment and personnel to treat specific medical conditions, or by interhospital variations in patient outcomes within a geographic region (Menke and Wray 2001). And in fact, the resources that are needed for these patients, like staff, are in limited supply. Regionalization is a way to optimize the use of those limited resources, by delivering the right patient to the right hospital, at the right time.

Theoretically we could say that our model has advantages:

1. Resources at CHP match the needs of the patients;
2. Better coordination of care during the acute phase;
3. Improved standardization of care within non-specialty hospitals;
4. Improved provision of scarce services;
5. NVAUGIB is a good example of an acute, time and expertise-dependent condition.

Weaknesses

Patient and family satisfaction are quite important. Regionalization means that patients are more likely to receive care far from home which may be a source of dissatisfaction. Another significant challenge is managing quality at the system level, which is very different from managing quality at a single facility or a single service within a facility. Data collection requires that data elements be standardized and that many different sources of information come together to be shared bi-directionally.

Theoretically we could say that our model has disadvantages:

1. Increased fixed costs and resources;
2. Travel time costs to hospitals and families;
3. Economic inefficiency if demand does not meet supply;
4. The risk of transfer;
5. Postdischarge follow-up care.

Pitfalls

An issue is associated with bypassing the closest hospital, without stabilization and preparation of a safe transfer. Another issue is the transfer of low risk patients or even non-bleeding patients, without previous communication, with misuse or overuse of resources.

In practice, how was our model's performance?

Research Question 1

The care provided in NVAUGIB was accessible and timely?

Most national and international guidelines recommend that EGD should be performed within 24h of presentation in patients with NVUAGIB (Palmer 2002; Barkun, Bardou et al. 2003; Palmer and Nairn 2008; Barkun 2010).

We did EGD to all patients directly admitted to ED-CHP or transferred from another hospital. Median time unit to out-of-hours endoscopy was 6h for direct admissions and 7.7h for transferred patients. Ninety percent of the patients were endoscoped in the first 24h.

On the other side, we analyzed the lead time for transferred patients, assuming time to endoscopy as the time from first ED admission to the endoscopy unit. This is issue is not mentioned in most of the studies by just referring to time as, time of admission in referral hospital, and others explicitly exclude transfer patients (Gralnek and Dulai 2004; Masaoka, Suzuki et al. 2007). Studies that mention the inclusion of patients transferred from another hospital didn´t analyze the outcomes in regard to the admission status (Phang, Vornik et al. 2000; Bjorkman, Zaman et al. 2004; Parente, Anderloni et al. 2005).

Our model performed better than previous reports from other centers. Previous papers reported that the accessibility of the patients to medical centers with experienced medical staff and adequate equipment was still limited in out-of-hours (Douglass, Bramble et al. 2005; Gibson, Hitchcock et al. 2006; Hearnshaw, Logan et al. 2010; Francisco José Martinez Cerezo 2011; Muthiah, Enns et al. 2012). The multi-centre cross sectional clinical audit performed in 2010 which involved over 75% of UK hospitals, collected data on 6750 patients (median age 68 years) from 208 hospitals. Although 92% of facilities had out-of-hours endoscopy available, only half had an endoscopy on call rota that would ensure an endoscopist to be available if needed. Of those endoscoped only 50% had an endoscopy within 24 h of presentation. The median time from presentation to endoscopy was 23 h (see above, 6h for ED-CHP and 7.7h for transferred patients). Most patients (59%) presented out of hours with 20% presenting between midnight and 8 am but the majority (82%) of endoscopies were performed during normal working hours. In our cohort, 52% of the NVAUIB patients presented out-of-hours: 46% between midnight and 4am; 41% between midnight and 4am and 13% from 4am to 8am. A percentage slightly different but explicable by the number of patients transferred, which inevitably arrived later at CHP. Another finding from this audit was that, as many as 42% of high risk patients (pre-endoscopy Rockall score >5) waited more than 24 h for their first endoscopy and 14% waited more than 72 h. Ninety percent of our patients had an endoscopy in less than 24h, whatever the admission status and risk stratification.

Research Question 2

The care provided in NVAUGIB was appropriate and effective?

Appropriateness is often treated as a single concept. However, there are two distinct types of appropriateness: appropriateness of a service and appropriateness of the setting in which care is provided. The differences between the two parallel the differences between two other concepts in health care: effectiveness and cost-effectiveness.

Compared with non-transferred patients, patients transferred from other hospitals had similar outcomes, similar to those reported in the literature, single center studies or population based studies. To our knowledge, transferred patients are not included as a comparable group or are excluded from some studies, as mentioned above.

An important issue of our study is that all patients with NVAUGIB, a part of risk stratification, had an endoscopy. This may be an area of some controversy. But the basic clauses are not in dispute and are supported by everyone: endoscopy is the most accurate and effective method for diagnosing the source of UGIB and treating most causes of NVAUGIB. Guidelines emphasize the importance of endoscopy within 24 h of presentation particularly for high risk patients (Barkun 2010). And 90% of our patients met this standard.

We can always question if early endoscopy, defined as an endoscopy performed in the first 24h, translate into more effectiveness and efficiency; if we should discharge low-risk patients without an endoscopy or, on the contrary, if early endoscopy allows early discharge of low risk patients; in this case we must endoscope all patients.

A systematic review of 23 studies analyzed the effectiveness of early vs. delayed endoscopy in low and high risk patients on patient and economic outcomes and concluded that early endoscopy is safe for all risk groups (Spiegel, Vakil et al. 2001). A recent review aimed to evaluate the optimal timing of early endoscopy by examining the findings of randomized clinical trials and retrospective cohort studies that used comparable outcome measures and have been reported in the literature (Tsoi, Ma et al. 2009). Of the 1,498 studies they have identified through database searches, 25 studies were selected for further scrutiny. They excluded 10 studies that focused on management of patients after early endoscopy and seven that did not report comparable outcome measures or only described management recommendations (Longstreth and Feitelberg 1995; Hsu, Lai et al. 1996; Lai, Hui et al. 1997; Rockall, Logan et al. 1997; Yen, Hu et al.

1997; Longstreth and Feitelberg 1998; Cebollero-Santamaria, Smith et al. 1999; Almela, Benages et al. 2001; Cipolletta, Bianco et al. 2002; Brullet, Campo et al. 2004; Tammaro, Di Paolo et al. 2008). Therefore, the discussion was based in the review of three randomized, controlled trials and five retrospective cohort studies published between 1996 and 2007(Lin, Wang et al. 1996; Cooper, Chak et al. 1998; Cooper, Chak et al. 1999; Lee, Turnipseed et al. 1999; Bjorkman, Zaman et al. 2004; Schacher, Lesbros-Pantoflickova et al. 2005; Tai, Huang et al. 2007; Targownik, Murthy et al. 2007). Interpretation of the results was limited by the heterogeneity of study designs: factors such as selection of patients, the use of different definitions of early endoscopy (which vary from 1 h to 48 h). Time to endoscopy was defined as the time since the patients were admitted to the emergency room or presented to hospital. Among the eight trials, two specifically excluded hemodynamically unstable patients (Lee, Turnipseed et al. 1999; Bjorkman, Zaman et al. 2004). Bjorkman and al. also excluded patients with severe comorbidities [Rockall score ≥6] (Bjorkman, Zaman et al. 2004). Targownik et al. just included hemodynamically unstable patients (Targownik, Murthy et al. 2007). Based on this review of eight studies, the authors concluded that early endoscopy may result in rapid hemostasis for high risk patients. In addition, early endoscopy may avoid hospitalization of low risk patients. A study has shown that early endoscopy significantly reduced rebleeding and surgery only in patients who required endoscopic hemostasis (Cooper, Chak et al. 1999). It has been shown, however, that the length of hospital stay is reduced for all patients who undergo early endoscopy, compared with those who undergo routine endoscopy, regardless of their need for therapy. For some authors there is no doubt that appropriate endoscopic therapy significantly reduces mortality, rebleeding, requirement for transfusion, hospital stay, and health-care costs (Cook, Guyatt et al. 1992). Of the 2 studies that conducted a cost-analysis, both found significant savings from early endoscopy (Hay, Maldonado et al. 1997; Lee, Turnipseed et al. 1999). In the study from Lee and al. 46% of patients who presented to the emergency department with AUGIB were discharged safely after endoscopic diagnosis and prognosis. Urgent endoscopy resulted in a 46% reduction in treatment costs and a 50% reduction in the length of hospital stay (Lee, Turnipseed et al. 1999). The value of preadmission endoscopy was realized only when the information obtained was used appropriately, namely, when low-risk patients were discharged. A second, almost identical study of urgent endoscopy performed in the emergency setting showed opposite results, because the emergency department physicians refused to discharge low risk patients (Bjorkman, Zaman et al. 2004).

In our case, if we have the support of physicians, nurses, equipment technicians and a well equipped facility, why should the procedure be delayed in high risk patients or why should low risk patients be discharged without the procedure? We can answer: it is time-consuming; that´s truth, but: time is already being paid and the patients' time also has its costs, as labor or transportation. No patient experience information is presented, however we believe that all patients would like to be discharged after endoscopy and return home earlier. Twenty percent (low and moderate high risk) and 4% (low risk) of the patients directly admitted to ED-CHP and transferred respectively, were discharged. So we argue that early endoscopy allows early identification of high risk patients and high levels of care and provides the opportunity for early discharge. Nevertheless, cost-effectiveness analysis of early endoscopy may not be the answer (Pedroto, Dinis-Ribeiro et al. 2012).

Research Question 3

The care provided in NVAUGIB was supported by best evidence and practice guidelines?

Recognized standards for these services include availability of endoscopically trained medical and nursing staff, access to a specialized endoscopy unit and full availability of the service. The procedure should only be done by consultant gastroenterologists with experienced endoscopic staff in the most appropriate setting, safeguarding and maximizing both, patient safety and procedure's effectiveness. Endoscopist's experience was also identified as an important prognostic factor for rebleeding and transfusion requirements in NVAUGIB, in a 2-year survey that prospectively assessed the impact of endoscopist's experience and time of endoscopy on the outcome; this study was conducted in a large tertiary referral center of western Milan, that also provides 24h emergency endoscopy for two district neighboring hospitals (Parente, Anderloni et al. 2005). Also, previous work has suggested that early involvement of endoscopists, such as that afforded by admission to the care of a dedicated in-patient gastroenterology service, can improve clinical and economic outcomes (Quirk, Barry et al. 1997).

In our out-of-hours service all the requirements for a safe and effective procedure, capacity, equipment and staff, are in place. In CHP, 30 consultant trained gastroenterologists from eight hospitals and sixteen skilled assistant staff from the endoscopy unit (eight nurses and eight endoscopy technicians) integrate the after-hours emergency gastroenterology team and are responsible for handling all gastroenterology emergencies, and decide not only when and how to perform EGD but also the planning for the patient, after the procedure.

Experienced endoscopy nurses and endoscopy technicians, that clean and reprocess the endoscopes are part of the team. In UK, just 37% (76/205) of the facilities had a nurse (trained in the use of therapeutic endoscopic techniques) on call endoscopy rota. A survey of the practice of after-hours and emergency endoscopy in Canada concluded that more than one-third of surveyed endoscopists across the country didn't have a trained endoscopy nurse to assist in after-hours endoscopy and that significant regional differences in the practice of after-hours endoscopy were observed (Muthiah, Enns et al. 2012). This is a quite disturbing finding as the need for appropriate technical assistance is more common during emergency procedures when haemostatic interventions are performed at a much higher rate than during the regularly scheduled procedures. But quality of care must be measured with continued and increased vigor. And clinical audit is a professionally way to participate in performance evaluation and a way to show accountability for quality of care. But clinical audit needs to be effective, by describing the exact improvement, select a strategy, design the change needed and operate the new way. This was not the case in UK. The two earlier surveys of the provision of out-of-hours endoscopy services in the UK (i.e., an on call rota of endoscopists) has not increased from the 50% reported by 150 hospitals in 2002 and the 49% reported in 2005(Douglass, Bramble et al. 2005; Gyawali, Suri et al. 2007). And in 2012, Jairath and al. published the results of a prospective audit that analyzed the outcomes of NVAUGIB in relation to time to endoscopy (Jairath, Kahan et al. 2012). Only 48% of endoscopies were performed within 24h and only 61% of the patients, classified with high risk stigmata of bleeding received therapeutic intervention. The emergency referral system was addressed in an Italian paper that concluded that in Lazio region, 30-day mortality rate from NVAUGIB, is lower when patients are admitted to EDs with greater resources (Cesaro, Kohn et al. 2013). The authors suggested the need for a better organization of the emergency referral system because high risk were less frequently referred to better levels of care. In our cohort, this does not seem to be a problem since, 15% of the patients had a clinical Rockall risk score ≥ 4 and after endoscopy, 60% were high risk patients.

If we analyze process indicators we met the standards in 80% to 90% of the cases with exceptions clearly defined which are much higher than those reported in other studies and in the clinical audits, mentioned above (table 15).

Table 15: Our Process Clinical Indicators

Criteria	Standard	Quality Dimension	Our Study
% of patients who had an endoscopy in the first 24h	100%	Effectiveness	90%
Direct admissions Transferred		Equity / Accessibility	88% 91%
% of patients who had an admission Rockall score	100%	Effectiveness	100%
% of patients who had acid suppression drugs before endoscopy	100% (guidelines before July 2012)	Effectiveness	80%
% of combined endoscopic treatment	100% Exceptions	Effectiveness	77% Exceptions: mechanical method
% of adrenaline monotherapy	0%	Effectiveness	4% Exceptions: uncontrolled bleeding; clot not removed
% of patients who repeated endoscopy when rebled	100% Exceptions	Effectiveness	100%
% of patients referred urgently for surgery when rebled and instable	100% Exceptions	Effectiveness	100%

Research Question 4

The care provided in NVAUGIB was safe and efficient?

In our study there is no evidence that early endoscopy resulted in patient's harm. Otherwise, it was a safe procedure: no adverse events were reported during transfer but two during endoscopy, namely, aspiration pneumonia and respiratory arrest; transient tachycardia, hypoxemia or self-limited bleeding were recorded as minor incidents in 4

patients. These rates are in agreement, even lower, than those reported in the current literature [<0.5%] (Ben-Menachem, Decker et al. 2012).

Another safety issue concerns decontamination practices. A survey of the practice of after-hours endoscopy in Canada reported that, in provinces where endoscopy nurses were not available on-call, endoscopists and/or residents were directly responsible for endoscope cleaning and reprocessing (Muthiah, Enns et al. 2012). The authors also stated that the absence of trained specialized staff for endoscope cleaning and decontamination appeared to be a direct consequence of the absence of an on-call endoscopy nurse. They concluded that, not only are the most critically ill patients not receiving optimal, specialized endoscopy care but endoscope reprocessing under these circumstances may be substandard, putting all endoscopy patients (urgent and routine) at risk. Also the Australian assessed 'after-hours' endoscopy services at Australian teaching hospitals using the British Society of Gastroenterology (BSG) criteria (Gibson, Hitchcock et al. 2006). Thirty-four centers (100%) provided complete data. The operation suite followed by the endoscopy unit were the most frequently used site. However, one-third of centers performed procedures at the bedside, including the emergency department or ward. Support staff was not consistently trained endoscopically and, in 15 centers (44%), the advanced trainees participated in the 'on call' roster with a consultant present for the procedure, although this was not consistently the case.

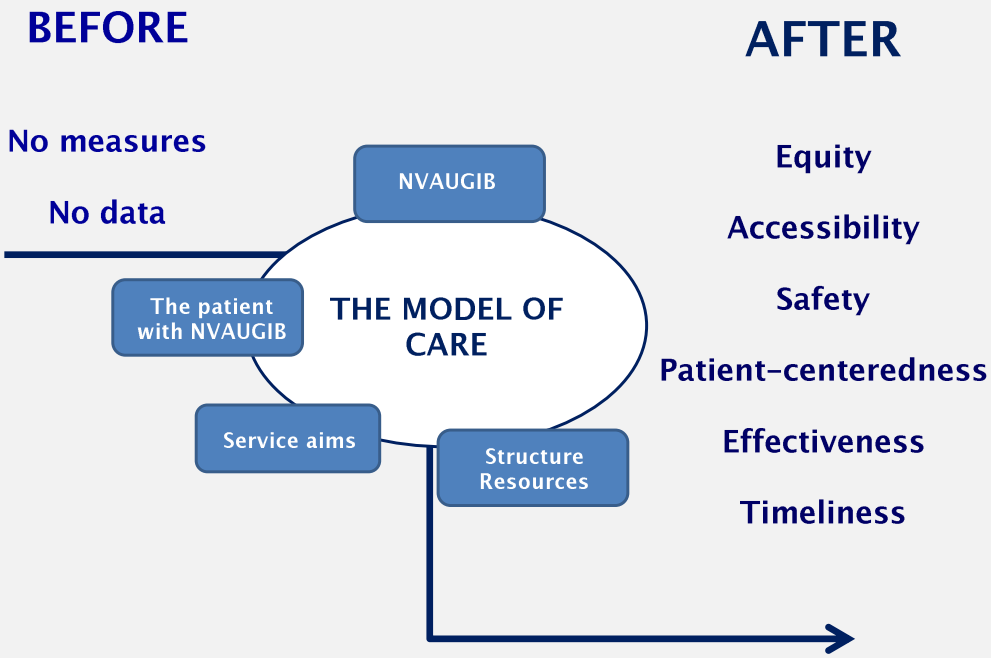
In contrast to previous surveys, in terms of infrastructure, staff and equipment we accomplish all the required criteria for clinical and non-clinical risk management.

If this model improved efficiency by taking a more strategic approach when allocating resources to a single unit, remains to be clearly answered. As discussed in paper III, we can probably assume potential savings in hospitals where endoscopy is only available from Monday to 2pm Friday and in those with difficulties in endoscopy arrangements, even on weekdays. Our next step is to know our costs by mapping the patient's journey: ED admission; transfer; endoscopy session; costs/bed/day. However, the recent guidelines published by the National Institute of Clinical Excellence reported that units with more than 330 presentations of AUGIB per year are cost effective with an everyday service (2012); they didn't take into account the weekend, with probably more income, which is our case. Nevertheless, cost-effectiveness analysis is a method for assessing the gains in health relative to the costs of different health interventions. We understand that the competitive worldwide economic environment and ever-increasing costs of health care have created a setting in which understanding costs and making sure that we achieve

good value in health care is crucial. Maybe our intervention model should be compared to others in Portugal. But, comparing interventions according to cost-effectiveness criteria must be done with a clear understanding that it compares interventions only in terms of their efficiency at improving health, and non-health benefits are not introduced into the debate, namely patient´s preferences, equity and accessibility. Many other issues may limit the value of an intervention and must be considered in decisions, including safety, adverse effects as to whether can be practically and widely applied.

Costs and benefits are not always tangible or can be expressed in monetary terms. I strongly believe that this emergency model of care offered added value in the management of NVAUGIB.

Figure 12: Before and After the Model's implementation and assessement



Ultimately, knowing which interventions work and at what cost has to be tempered by knowledge of their performance. Only when scientific and practical knowledge are combined can policy makers identify the interventions that will have the most impact in practice.

Thus the performance analysis presented in this thesis provides an important contribution to broader debates about public policy decisions pertaining emergency care in gastroenterology.

Strengths of our study	Research questions 1-3
Limitations of our study	Research question 4, efficiency

CHAPTER VI
CONCLUSIONS

VIa. Concluding Remarks
VIb. Practical Implications
VIc. Further Research

CHAPTER VI
CONCLUSIONS

VIa. Concluding Remarks

VIb. Practical Implications

VIc. Further Research

VI. CONCLUSIONS

VIa. Concluding Remarks

Improving the quality of healthcare through the best scientific evidence available in a context of scarce resources is a challenge for all the health systems.

As it was a challenge to think about the quality of emergency care in NVAUGIB and how it was organized to provide high quality of care to every patient, every time it is needed. Nevertheless I believe we, as clinicians, have an increasingly important role and responsibility in the quality of care being offered to patients. But, only quality data can enable valid conclusions to be drawn, which in turn enable changes to be made for the better. It is therefore necessary to increase the understanding of the causes affecting the quality of care, their effects on the quality of such care and how their management can be improved.

There are some longer-term issues that have been raised in this analysis that are worth considering:

1. Out-of-hours endoscopy is a major issue, with large and important regional variations in process and outcomes, not explained by differences in patient characteristics.

2. Most countries lack a well-coordinated approach to acute bleeding.

3. Barriers to implementation include economic constraints, lack of resources and infrastructure.

4. Position statements don´t specifically address after-hours or emergency endoscopy.

5. Out-of-hours endoscopy seems to be out of some quality dimensions.

6. Concerning our research in NVAUGIB, a great deal of work has been done and significant progress has been made but achieving the goal of a system that is capable of working as a whole is not an easy task. In some cases there is a need to rethink how the system is managed, to pay attention to flow through the whole

system, the speed at which these different parts work and how they interact to create a better flow through, as explained in this thesis. Attention was given to what happens to patients before they are referred to URGE, but not to the services available to them after discharge or transfer. They are part of a wider system and more thought is required about how the system as a whole operates together and new measures and data may support this.

7. However, this regionalization model has avoided more fragmentation and improved equity and accessibility in a safety and effectiveness manner.

8. It has overcome the problem of emergency provision: the workforce, which must be defined and adequate qualitatively and quantitatively.

CHAPTER VI
CONCLUSIONS

VIa. Concluding Remarks

VIb. Practical Implications

VIc. Further Research

VI. CONCLUSIONS

VIb. Practical Implications

1. The strategy to improve care demonstrated equity, safety, efficiency, timeliness and availability of appropriately trained and experienced endoscopy staff.

2. Scarce health care resources were allocated wisely and fairly.

3. Median time to out-of-hours endoscopy was 6h for direct admissions and 7.7h for transferred patients; 90% of the procedures were performed in less than 24h.

4. Age, malignancy and an admission Rockall risk score were predictors of in-hospital mortality, whatever the admission status.

5. Rates for rebleeding, mortality and need for surgery were similar in transferred vs. direct admissions.

Resources are limited, and health care must be allocated efficiently, but, equity and patient-centeredness are crucial dimensions of quality of care.

The coordinated actions of diverse institutions providers are an essential component; clinical guidelines, including safe transfer, must be implemented, disseminated and quality continuous monitored.

This may fit in a larger opportunity to improve processes and outcomes in this and other clinical contexts.

Nevertheless it is important to determine, in the near future, the impact of regionalization in the economics of hospitals within the system.

CHAPTER VI
CONCLUSIONS

VIa. Concluding Remarks

VIb. Practical Implications

VIc. Further Research

VI. CONCLUSIONS

VIc. Further Research

In this overview we have shown that regionalized care for NVAUGIB, although compelling, is incomplete.

Recommendations for future areas of research should focus on:

1. Costs of care using cost-effectiveness or cost-utility analysis;

2. Examination of interhospital variations, particularly within hospitals with similar characteristics;

3. Compare the changes to similar areas who did not experience the reorganization.

4. Measures of patient satisfaction and preference.

APPENDIX

ARS NORTE
Administração Regional de Saúde do Norte, I.P.

URGÊNCIA REGIONAL DE GASTRENTEROLOGIA (URGE)

GESTÃO CLÍNICA DA HEMORRAGIA DIGESTIVA ALTA

Normas Orientadoras Clínicas

Aprovadas pelo Conselho Directivo da ARS-Norte, IP, em Março de 2010

Documento de Trabalho elaborado para a ARSN

A ser distribuído por todos os Serviços de Gastrenterologia da URGE e da ARS Norte

Elaborado por: Isabel Pedroto e Fernando Magro

Revisto por: Jorge Areias; Costa Santos; José Pedrosa; José Cotter; Rute Cerqueira

Elaborado em Outubro de 2009 e Revisto em Março de 2010

NOTAS PARA A SUA UTILIZAÇÃO

NOTAS PARA A SUA UTILIZAÇÃO

As recomendações contidas neste documento são formuladas para um grupo de doentes nos quais se desenha um determinado fluxo de processos, actividades e tarefas; a decisão clínica deve ser sempre individualizada, combinando estas guias de orientação clínica com a avaliação clínica. Quaisquer desvios significativos destas recomendações devem ficar claramente explícitos e justificados nos registos clínicos.

Abreviações usadas no texto

HD	Hemorragia digestiva
HDA	Hemorragia digestiva alta
EDA	Endoscopia digestiva alta
HDB	Hemorragia digestiva baixa
PR	Pulso radial
TA	Tensão arterial
FR	Factores de Risco
TP	Tempo de protrombina
HP	Helicobacter Pylori
IBP	Inibidor da bomba de protões
ECG	Electrocardiograma
Hb	Hemoglobina
VG	Volume globular
AINE's	Anti-inflamatórios não esteróides
CGR	Concentrado de Glóbulos Rubros
PTFC	Plasma Total Fresco Congelado
INR	Razão normalizada internacional

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INTRODUÇÃO

A HDA constitui a causa mais frequente de urgência/emergência Gastroenterológica. No caso da hemorragia digestiva alta não-varicosa a mortalidade, não obstante o avanço nas terapêuticas endoscópica e farmacológica não se modificou na última década. A causa deste fenómeno correlaciona-se fundamentalmente com três aspectos: 1) a faixa etária dos doentes; 2) a coexistência de comorbilidades significativas; 3) o maior uso de AINE's e outros fármacos como os anti-agregantes plaquetários.

A reestruturação da urgência de gastrenterologia, actualmente designada de URGE (Urgência Regional de Gastrenterologia) resultou da necessidade de gerir de forma mais eficaz e eficiente os recursos humanos existentes.

Os objectivos subjacentes a este projecto passavam, no imediato, por dar resposta às necessidades de endoscopia de urgência. No entanto, para que este apoio seja realizado de uma forma eficiente e sustentada, torna-se imperativo a implementação de regras: o doente percorre todo um fluxo de processos, desde que é admitido num serviço de urgência até que realiza endoscopia (nessa ou noutra instituição), tem alta, é internado ou transferido, e cujos elos são facilmente fragilizados pela ausência de normas e coordenação de cuidados.

A implementação de uma gestão clínica da URGE visa potenciar a eficácia, manter actualizada uma estrutura organizativa uniforme, e possibilitará a elaboração de relatórios de gestão clínica através de uma monitorização contínua da prática baseada em indicadores de qualidade e segurança.

Objectivos:

1. **Operacionais**

Melhorar a gestão clínica do doente com HD:

- a referenciação para endoscopia;
- o transporte;
- a escolha e utilização de fármacos e sangue ou derivados;
- a admissão e alta do doente com HD;
- a redução da variabilidade na prática clínica;
- a estratificação do risco (registo de complicações/mortalidade).

2. **Organizacionais**

- coordenar dos vários profissionais envolvidos no tratamento do doente com HD;
- optimizar o uso da endoscopia na urgência.

RECOMENDAÇÕES NA AVALIAÇÃO DA HEMORRAGIA DIGESTIVA ALTA

Recomendações Gerais

A imediata avaliação clínica e apropriada estabilização hemodinâmica são fundamentais no prognóstico dos doentes com hemorragia digestiva alta. Os parâmetros clínicos são essenciais na triagem para determinar o nível de cuidados e a oportunidade de realização da endoscopia.

As comorbilidades devem ser tratadas agresssivamente mantendo uma adequada perfusão de orgãos.

Constituem aspectos críticos na avaliação inicial: a gravidade e actividade da hemorragia; a localização da lesão sangrante (alta vs baixa); hemorragia varicosa ou não-varicosa; a coagulopatia associada.

Esta abordagem é, sempre que possível, multidisciplinar: Gastroenterologista, Internista, Intensivista e Cirurgião.

A estratificação do risco de acordo com a gravidade da doença e o potencial de resultados adversos permite uma melhor gestão clínica e de recursos: alta precoce ou endoscopia urgente. A estratificação do risco é um processo dinâmico no decurso da evolução clínica do doente: 1º) na apresentação clínica; 2º) na endoscopia; 3º) pós-endoscopia.

Embora a endoscopia precoce seja um procedimento chave, quando realizada em doentes inadequadamente estabilizados coloca em risco a sua segurança.

A razão básica para a transferência inter-hospitalar de um doente hemorrágico baseia-se na necessidade de cuidados adicionais, ou técnicos ou de outras especialidades, não disponíveis (em tempo considerado útil) na instituição local.

O período do transporte de um doente agudo é um período de potencial instabilidade. Se a intervenção considerada não vai alterar o manuseamento clínico nem o prognóstico do doente, o transporte deve ser questionado (potenciais benefícios vs potenciais riscos) pois nunca deve comprometer a segurança do doente.

Nenhum algoritmo ou guia de orientação clínica ou plano de transferência inter-hospitalar substitui o diálogo entre o clínico que transfere o doente, responsável pelo transporte, e o clínico que aceita o doente, responsável por activar todos os mecanismos necessários à recepção, em coordenação com os demais intervenientes da equipa.

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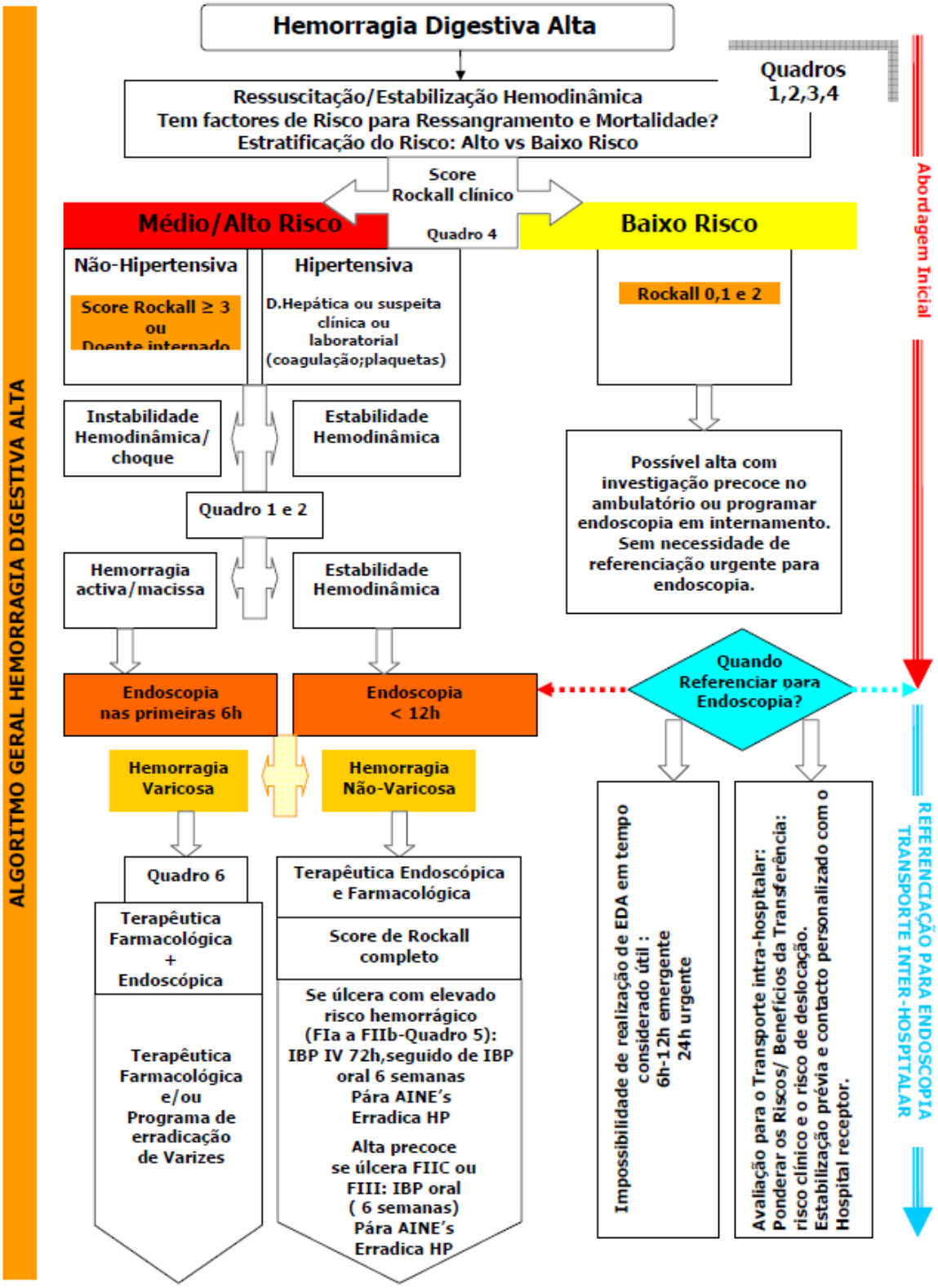
ALGORITMO GERAL HEMORRAGIA DIGESTIVA ALTA
Hemorragia Digestiva Alta
Quadros 1,2,3,4
Ressuscitação/Estabilização Hemodinâmica
Tem factores de Risco para Ressangramento e Mortalidade?
Estratificação do Risco: Alto vs Baixo Risco
Score Rockall clínico
Quadro 4
Médio/Alto Risco
Baixo Risco
Não-Hipertensiva
Score Rockall ≥ 3 ou Doente internado
Hipertensiva
D.Hepática ou suspeita clínica ou laboratorial (coagulação;plaquetas)
Rockall 0,1 e 2
Instabilidade Hemodinâmica/ choque
Estabilidade Hemodinâmica
Quadro 1 e 2
Possível alta com investigação precoce no ambulatório ou programar endoscopia em internamento. Sem necessidade de referenciação urgente para endoscopia.
Hemorragia activa/macissa
Estabilidade Hemodinâmica
Quando Referenciar para Endoscopia?
Endoscopia nas primeiras 6h
Endoscopia < 12h
Hemorragia Varicosa
Hemorragia Não-Varicosa
Quadro 6
Terapêutica Farmacológica + Endoscópica
Terapêutica Farmacológica e/ou Programa de erradicação de Varizes
Terapêutica Endoscópica e Farmacológica
Score de Rockall completo
Se úlcera com elevado risco hemorrágico (FIa a FIIb-Quadro 5): IBP IV 72h,seguido de IBP oral 6 semanas Pára AINE's Erradica HP
Alta precoce se úlcera FIIC ou FIII: IBP oral (6 semanas) Pára AINE's Erradica HP
Impossibilidade de realização de EDA em tempo considerado útil : 6h-12h emergente 24h urgente
Avaliação para o Transporte intra-hospitalar: Ponderar os Riscos/ Benefícios da Transferência: risco clínico e o risco de deslocação. Estabilização prévia e contacto personalizado com o Hospital receptor.
Abordagem Inicial
REFERENCIAÇÃO PARA ENDOSCOPIA TRANSPORTE INTER-HOSPITALAR

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Quadro 1: Manobras Iniciais de Rotina

Parâmetros Vitais	TA; FC; FR; Sat.O2; Estado de consciência
Acesso Venoso	
Laboratório	Hemograma, sódio, potássio, ureia, creatinina, AST, ALT, Bilirrubina total, INR, aPTT
Provas Sangue	
ECG	
SNG	
Rx Tórax	
DOENTE INSTÁVEL	
Monitorização Contínua	TA, FC, O2,Diurese,ECG
Acesso Venoso	Dois e eventual CVC
Infusão rápida de solução fisiológica	Sangue O negativo

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Quadro 2

	Fármacos
Solução Fisiológica	1000-2000ml IV
Pantoprazol	80 mg IV em bolus seguido de 8mg/h durante 72h
Esomeprazol	Bolus de 80mg seguido de 40mg 12/12h IV
Terlipressina	Bolus de 2mg seguido de 2mg 4/4h IV
Octeótrido	Bolus de 50ug seguido de 25-50ug/h em perfusão contínua em Soro fisiológico. (se contraindicação para a terlipressina)
Eritromicina	Bolus de 250mg IV ou infusão contínua durante 30 minutos de 3mg/Kg
	Sangue, Plasma ou Factores
Sangue O negativo	Hemorragia macissa com choque
CGR	Hb < 7 g/dL ou < 8-9g/dL de acordo com as comorbilidades e a etiologia (hipertensiva vs não-hipertensiva)
PTFC	10-20ml/Kg
Factor VIIa recombinante	15-90mcg/Kg
Complexo protrombínico	25-50U/kg
Plaquetas	1-2 (se 70Kg, 1 pool aumenta a contagem plaquetária de 20-25000/mcl

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Quadro 3: Factores de Risco para Ressangramento e Mortalidade

	Clínicos
Anamnese	Idade > 70 anos Comorbilidades: Insuf. Renal, Insuf. Cardíaca, Insuf. Hepática, Neoplasia.
Parâmetros Vitais	Instabilidade Hemodinâmica TA sistólica < 100mmHg Pulso > 100 ppm Estado Confusional
Sangramento	Sangue vivo no aspirado gástrico Sangue vivo ao toque rectal Persistente ou Ressangramento
	Laboratoriais
	Aumento Ureia Aumento creatinina Hemoglobina < 10g/dL Coagulopatia: INR > 1,5 Plaquetas < 50000
	Endoscópicos
	Neoplasia do tubo digestivo alto Sangramento em jacto, toalha, vaso visível ou coágulo aderente. (Forrest Ia, Ib, IIa, IIb)

Quadro 4: Estratificação do Risco – Score de Rockall

Variável		Pontuação			
		0	1	2	3
Idade (anos)		<60	60-79	=80	
Hemodinâmica	Pré-Endoscópico		Frequência cardíaca > 100 /minuto	TA sistólica < 100 mmHg	
Comorbilidades	Pré-Endoscópico			Doença cardíaca isquémica Insuficiência cardiaca congestiva outra comorbilidade *major*	Insuficiência renal Insuficiência hepática Neoplasia metastizada
Diagnóstico Endoscópico	Endoscópico	Mallory-Weiss ou nenhuma lesão	Úlcera péptica Esofagite erosiva	Doença maligna do aparelho digestivo	
Estigmas de hemorragia recente	Endoscópico	Úlcera de base limpa ou com Pigmento hemossidérico		Sangue no tubo digestivo, Coágulo, vaso visível ou hemorragia em jacto	

Score Clínico (antes da EDA)= idade + hemodinâmica + comorbilidades

Score completo (após a EDA)= score clínico + diagnóstico endoscópico + estigmas de hemorragia

Score máximo: antes da endoscopia =7; após diagnóstico endoscópico=11

Estratificação final do risco:

Baixo: ≤ 2
Intermédio: 3-4
Alto: ≥ 5

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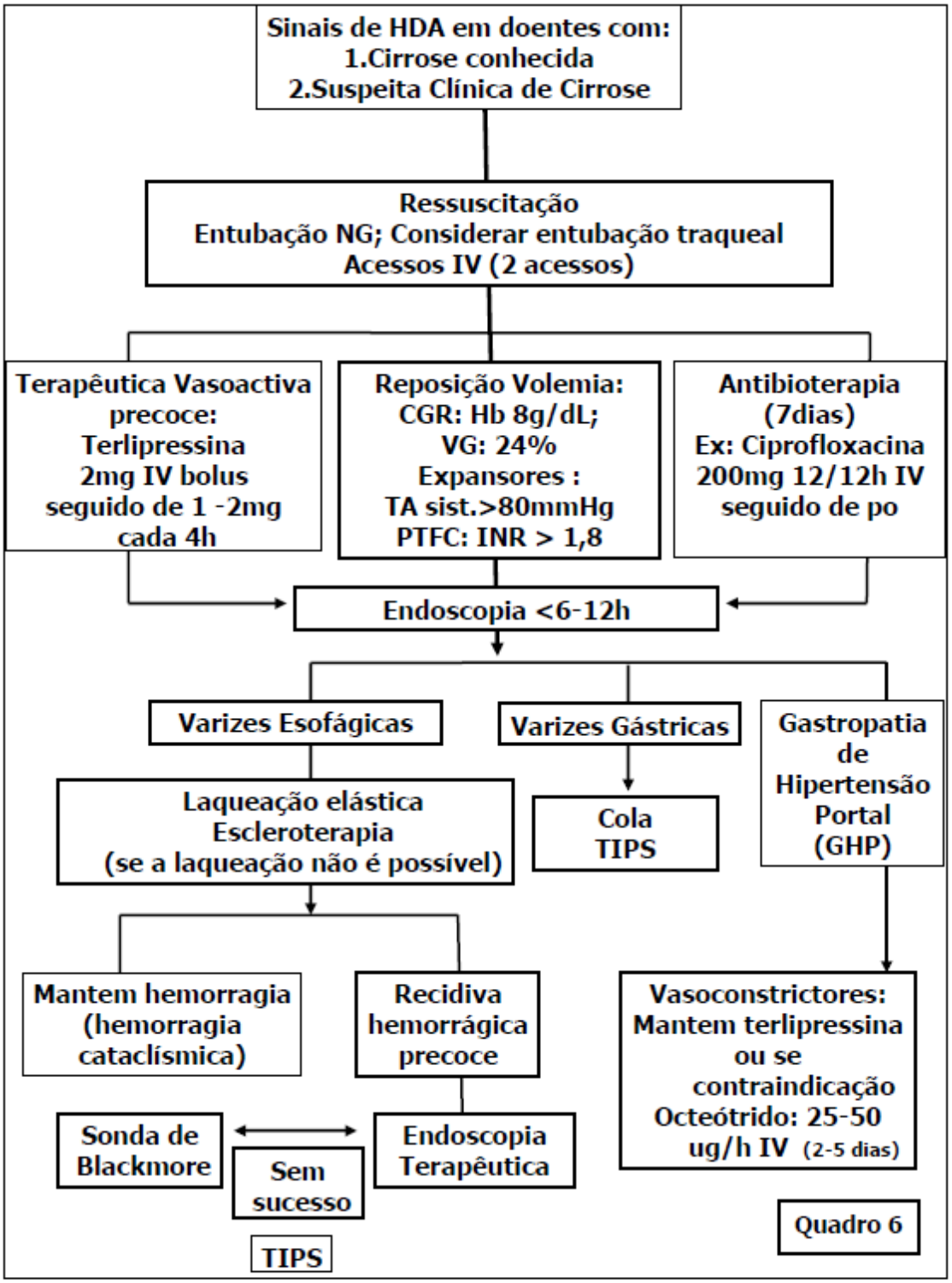
Score Rockall (pontos)	Mortalidade (%)
3	3%
4	6%
5	12%
6	17%
7	27%
8	40%

A ENDOSCOPIA

Quadro 5 : Risco de Recidiva Hemorrágica de acordo com a Classificação de Forrest

Classificação Forrest	Endoscopia	Recidiva Hemorrágica %	Cirurgia %	Mortalidade %
Ia, Ib	Hemorragia activa	55	35	11
IIa	Vaso Visível	43	34	11
IIb	Coágulo aderente	22	10	7
IIc	Pigmento hemossidérico	10	6	3
III	Base limpa	5	0.5	2



Tratar o Doente, não só a hemorragia
A Transfusão, a Infecção e o Rim

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RECOMENDAÇÕES **Avaliação Clínica Inicial e Estabilização**

Como estabilizar o doente?

Recomendação I

No doente com hemorragia digestiva alta a avaliação clínica inicial e uma adequada estabilização hemodinâmica são prioritárias e fundamentais. A intensidade das medidas de ressuscitação é proporcional à severidade da hemorragia.

a) A correcção da hipovolemia é o objectivo prioritário da reanimação inicial; aconselha-se a administração tanto de colóides como de soro fisiológico; 1-2 litros de solução fisiológica é geralmente suficiente para corrigir as perdas mas em caso de hemorragia maciça pode ser necessário associar CGR O negativo;
b) Através de dois acessos venosos (14-18G);
c) Monitorização contínua da TA e FC até paragem da hemorragia; horária nas 12h seguintes e depois cada 4h; diurese horária se choque; Sat.O2.

Quando e como transfundir?

Recomendação II

A administração de CGR deve ser considerada em todos os doentes em choque, instáveis mesmo após a reposição de volume e nos restantes de acordo com a estratificação de risco e a etiologia da hemorragia: hipertensiva vs não-hipertensiva.

HDA Não-Hipertensiva	HDA Hipertensiva
• Sangramento maciço com choque (considerar CGR O-) • Instabilidade hemodinâmica apesar da correcção da hipovolemia • Hb < 7g/dl • Hb <8-9g/dl : se patologia cardio-respiratória associada ou idade ≥ 65 anos • 7>Hb<9g/dl: decisão clínica individual • Transfusão de Plaquetas se < 50000 • INR > 1,5: Vitamina K associada a factor VIIa recombinante ou complexo protrombínico ou PTFC	• O alvo transfusional é: Hematócrito de 24% e/ou Hemoglobina de 8g/dL. excepto se comorbilidades associadas como doença cardíaca Coagulação: Sem recomendações mas empiricamente sugere-se: PTFC: 1 unidade por cada 4 U de CGR Vitamina K: 10mg IV dose única

DEVE SER CONSIDERADA A ENTUBAÇÃO NASO-TRAQUEAL SE SANGRAMENTO MACIÇO OU PERTURBAÇÃO DO ESTADO DE CONSCIÊNCIA (risco de aspiração).

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RECOMENDAÇÕES **Avaliação Clínica Inicial e Estabilização**

Porquê a Sonda Naso-Gástrica?

Recomendação III

A sonda nasogástrica é benéfica para detectar a presença de sangue, determinar a gravidade da hemorragia, preparar o campo de visualização endoscópico e prevenir a aspiração de conteúdo gástrico.

A drenagem gástrica, não traumática, de sangue confirma a hemorragia digestiva alta; sangue vivo e coágulos frescos sugerem hemorragia activa enquanto a presença de sangue digerido (*"borra de café"*) são sugestivos de hemorragia recente.

A drenagem contínua de sangue vermelho vivo associa-se a hemorragia activa severa.

A ausência de sangue não exclui hemorragia digestiva alta.

Recomendação IV

Estratificação do Risco Clínico: Quando e Como

Se não existe qualquer dúvida que a hospitalização é mandatória na hemorragia digestiva varicosa nos doentes cirróticos, a hemorragia digestiva não-varicosa é inconstante na sua apresentação, com um espectro alargado de gravidade clínica.

A gravidade clínica da apresentação condiciona as necessidades transfusionais, a mutidisciplinaridade da abordagem clínica, o local de internamento, a urgência da realização da endoscopia digestiva, a necessidade de referenciação dos doentes a um gastroenterologista e consequentemente e por vezes a decisão de um transporte secundário.

O **score de Rockall** combina factores clínicos e factores endoscópicos no sentido de estratificar o risco de eventos adversos decorrentes do episódio de hemorragia digestiva não-varicosa.

O **score de Rockall** clínico deve ser sistematicamente realizado na primeira abordagem clínica do doente hemorrágico (e sempre que uma instituição recepciona o doente).

Após a estratificação do risco clínico o doente deve ser orientado para vigilância e cuidados adequados à gravidade da situação clínica, em unidade de cuidados intensivos, unidade de intermédios, enfermaria ou mesmo alta hospitalar.

RECOMENDAÇÕES Endoscopia

Recomendação V

Quando Referenciar para Endoscopia?

O doente deve ser referenciado para endoscopia de acordo com os **algoritmos gerais** ou seja:

I. Após Estabilização cardio-circulatória;
II. Após Estratificação do Risco Clínico: Score de Rockall;
III. Após contacto com o Gastrenterologista: endoscopia urgente/emergente/alta precoce (realização de EDA sem indicação urgente e posterior orientação para ambulatório).

Deve ser considerada a referenciação à urgência regional:
(transporte do doente-recomendação VI)

Se:

Impossibilidade de realização de EDA em tempo considerado útil:
Nas primeiras 6h: emergente
Nas primeiras 12h: urgente

E após:

Ponderar os Riscos/ Benefícios da Transferência

Recomendação VI

O Transporte do Doente

A razão básica para a transferência inter-hospitalar de um doente hemorrágico baseia-se na necessidade de cuidados adicionais, ou técnicos ou de outras especialidades, não disponíveis na instituição local (em tempo considerado útil).

O acompanhamento do doente é determinado pelo algoritmo definido pelas recomendações internacionais de transferência inter-hospital considerando a efectividade do mesmo: a segurança e a morbilidade e mortalidade associadas à transferência.

O planeamento do transporte engloba 5 pontos:

- Antes do transporte: coordenação e comunicação multidisciplinar;
- Profissionais que acompanham o doente;
- Equipamento necessário;
- Monitorização durante o transporte;
- Documentação.

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RECOMENDAÇÕES **Endoscopia**

Recomendação VII

A Recepção do Doente na URGE

A triagem de Manchester estabelece uma triagem de prioridades, dando a conhecer a prioridade clínica e o tempo alvo recomendado a que o doente deve obedecer até à observação médica.

Sempre que o doente é admitido numa Instituição Hospitalar deve ser avaliado/reavaliado clinicamente em termos de gravidade clínica da hemorragia: estratificação do risco clínico, antes de qualquer abordagem endoscópica, independentemente da prioridade que lhe foi atribuída.

Esta abordagem deve ser, sempre que possível, multidisciplinar. No caso de transferência intra-hospitalar, o transporte pode traduzir-se por instabilidade para o doente com agravamento do quadro clínico.

Neste momento devem ser de novo equacionados os critérios de gravidade clínica da hemorragia (estratificação de risco) e a orientação do doente para vigilância e cuidados adequados à gravidade da situação clínica, seja em unidade de cuidados intensivos, unidade de cuidados intermédios, enfermaria ou mesmo alta hospitalar.

A oportunidade de realização da endoscopia digestiva é definido pelo Gastorenterologista.

(Algoritmos gerais de avaliação inicial e triagem de doentes com hemorragia digestiva).

Recomendação VIII

O Exame Endoscópico

A Endoscopia Digestiva deve ser realizada no Centro de Endoscopia, local adequadamente equipado; em casos específicos de doentes em choque, com dificuldade de estabilização hemodinâmica, ou se necessitarem de apoio anestésico, a endoscopia deverá ser realizada na sala de emergência ou no bloco operatório.

O local de realização do exame endoscópico é da responsabilidade do Gastroenterologista e demais especialistas intervenientes, os quais em conjunto avaliam a gravidade da situação hemorrágica e consequentes recursos necessários.

Caso haja necessidade de realização no Bloco Operatório com apoio de anestesista a realização da endoscopia digestiva deve ser priorizada em conjunto com os demais procedimentos/intervenções.

A **administração de eritromicina** endovenosa (bólus de 250 mg ou infusão de 3mg/kg durante 30 minutos) 20 a 90 minutos antes da realização da endoscopia pode me-

RECOMENDAÇÕES **Endoscopia**

lhorar a qualidade do exame por permitir um esvaziamento gástrico de sangue e coágulos, podendo, assim, ser útil em casos de hemorragia grave.

Recomendação IX

A Estratificação do Risco Pós-Endoscópico

A Estratificação do Risco Pós-Endoscópico deve ser sempre realizada e obtemos o score de Rockall final.

É importante ressalvar que existem outros factores endoscópicos predizentes de mau prognóstico: o tamanho da úlcera (> 2cm) e a localização (parede posterior do bolbo duodenal e parte alta da pequena curvatura do corpo.

A classe de Child-Pugh, a disfunção renal, a infecção, a presença de hemorragia activa na endoscopia, o consumo activo de álcool, trombose da veia porta e o carcinoma hepato-celular constituem factores de pior prognóstico na hemorragia digestiva alta de causa hipertensiva.

RECOMENDAÇÕES **Terapêutica Farmacológica**

Recomendação X

A Terapêutica Médica deve iniciar-se de imediato, sempre antes da endoscopia.

Inibidores da Bomba de Protões (IBP)	Fármacos Vasoactivos
Doentes com suspeita de hemorragia por úlcera devem iniciar terapêutica com IBP endovenoso.	Em doentes com história conhecida de cirrose hepática ou hipertensão portal ou suspeita de doença hepática crónica, a terapêutica com fármaco vasoactivo deve ser imediatamente iniciada.
Sempre um bolus de 80mg IV seguido de perfusão contínua de 8mg/h (ou oral de acordo com os achados endoscópicos.)	**Droga de 1ª escolha Terlipressina** 1-2 mg, bólus endovenoso 4/4h (1 mg se peso<50 kg, 1,5 mg se peso 50-70 kg e 2 mg se peso>70 kg) **Cuidados:** ECG e monitorização cardíaca. (SEMPRE)

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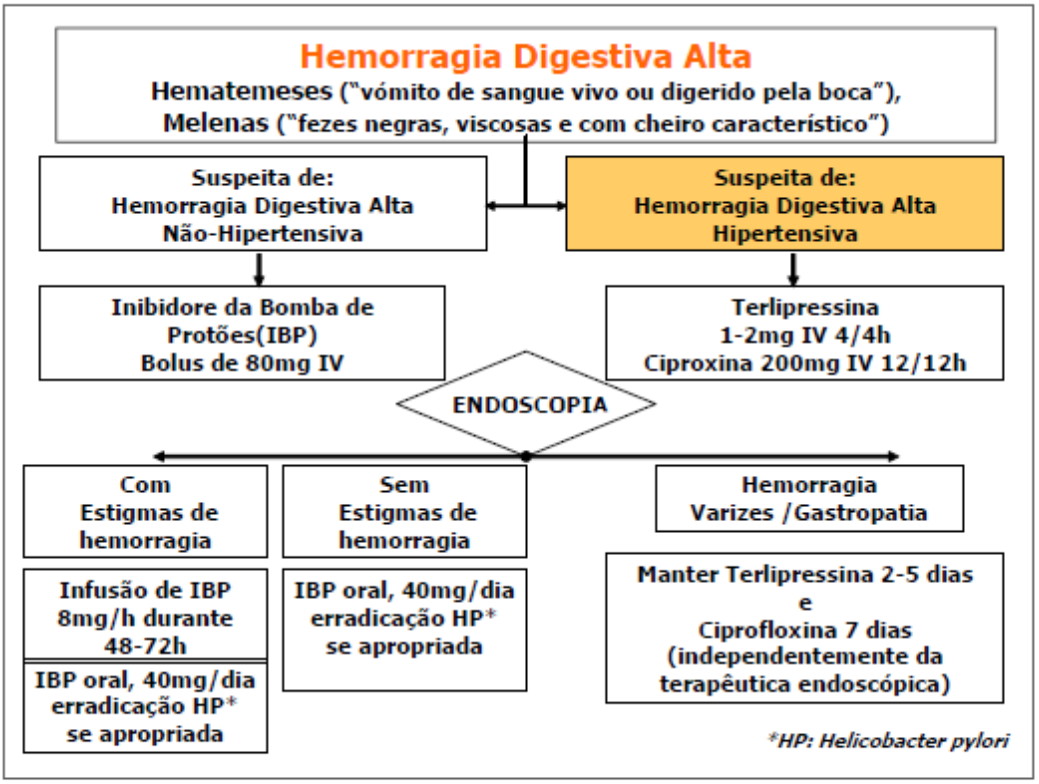
	Contra-indicações: história de cardiopatia isquémica, acidente vascular cerebral, doença vascular periférica e arritmias cardíacas. **Alternativas**, se contraindicações: **Octeótrido** 50 µg, bólus ev, seguido de infusão contínua a 25-50 µg/h IV: **Somatostatina** 250 µg, bólus ev seguida de infusão contínua a 250 µg/h IV.

Todos os doentes com cirrose hepática e hemorragia digestiva apresentam um risco elevado de infecção (factor condicionante de recidiva hemorrágica e da mortalidade), sendo mandatória a profilaxia antibiótica durante 7 dias - norfloxacina 400 mg 12-12h oral, ou quando a via oral não é possível, ciprofloxacina 200 mg 12-12h ev ou ceftriaxone 1 gr /dia ev.



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A sonda de Sengstaken-Blakemore

O uso do **Tamponamento com Balão** está condicionado às seguintes situações:

1. Casos de hemorragia varicosa esogástrica cataclísmica constituindo uma ponte para uma nova abordagem terapêutica.
2. Hemostase parcial (elevada probabilidade de recidiva).

O **tamponamento com balão** actuando por pressão mecânica directa é limitado pelas elevadas taxas de recidiva hemorrágica e complicações (40% dos casos com uma mortalidade de 20-30%: aspiração pulmonar, necrose/perfuração esofágica, fístula traqueo-esofagica e migração com obstrução brônquica).

A sonda de **Sengstaken-Blakemore (TSB)** contém 2 balões gástrico e esofágico sendo o volume do balão gástrico de aproximadamente 250-300mL e o do balão esofágico de 75mL. Embora a duração ideal seja controversa o balão esofágico não deve permanecer insuflado mais de 24h e o gástrico 24-48h.

RECOMENDAÇÕES — Seguimento

Onde Internar o Doente?

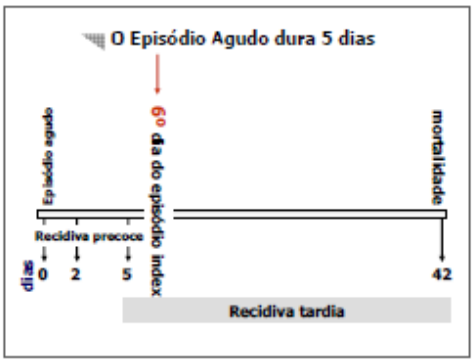
Recomendação XI

⇒ Hemorragia Digestiva Não-Hipertensiva:

O local de internamento deve ser sempre equacionado caso a caso, tendo em consideração a estratificação do risco, o risco de recidiva hemorrágico e os recursos disponíveis na instituição receptora e na instituição emissora.

⇒ Hemorragia Digestiva Hipertensiva:

Todos os cirróticos devem ficar internados durante, pelo menos 5 dias e sempre numa unidade de intermédios/intensivos (equacionado caso a caso) nas primeiras 24h ou tratando-se de um primeiro episódio de hemorragia digestiva.

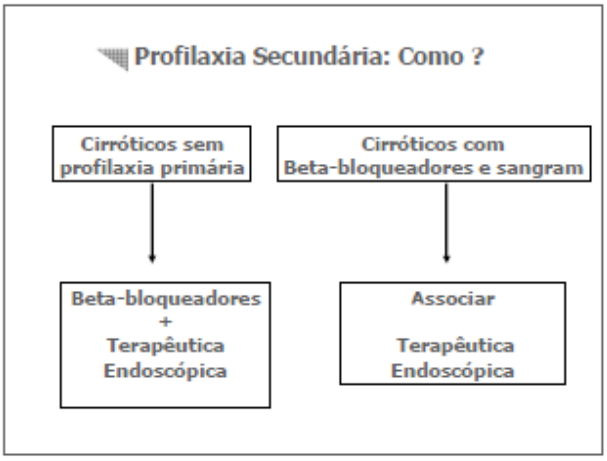


Nos cirróticos em tratamento profiláctico primário com β-bloqueadores e que sangram de varizes esofágicas a laqueação elástica é associada.

RECOMENDAÇÕES Seguimento

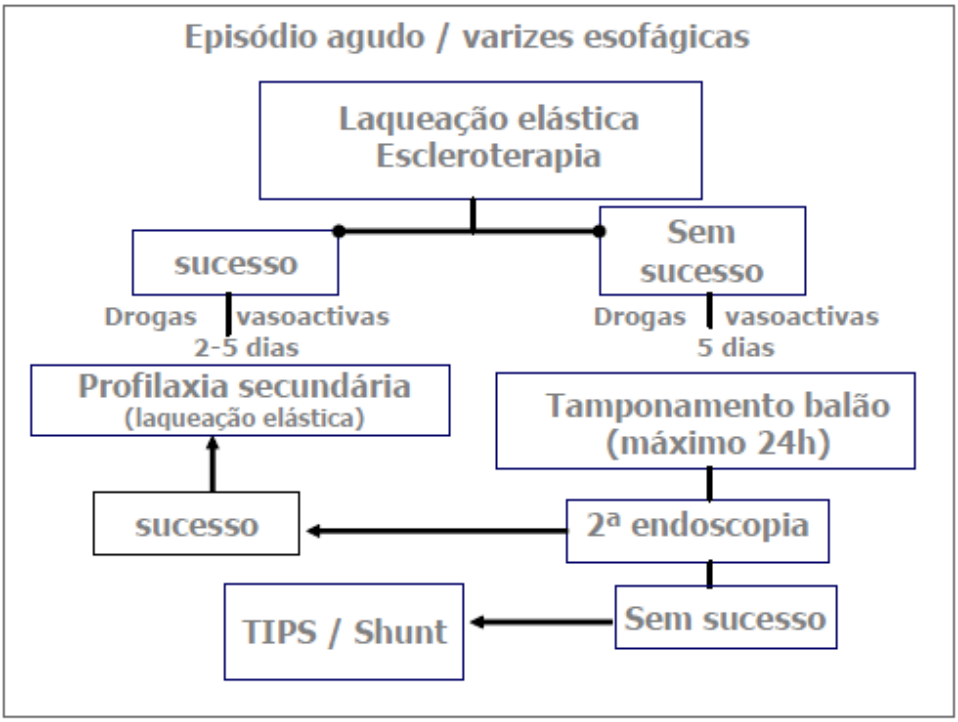
Nos cirróticos que sangram pela primeira vez, sem qualquer terapêutica prévia instituída, a combinação β-bloqueadores e laqueação elástica parece constituir a melhor opção terapêutica.

A terapêutica endoscópica isolada reserva-se para os cirróticos com contraindicações para os β-bloqueadores.



Após evidência de hemorragia por gastropatia de hipertensão portal inicia-se terapêutica com β-bloqueadores; como nas outras situações a decisão de tratar é condicionada pela presença de contraindicações tais como: doença pulmonar crónica obstrutiva, bloqueio aurículo-ventricular e insuficiência arterial periférica; a bradicardia sinusal e a diabetes mellitus insulino-dependente são contraindicações relativas. Iniciada a terapêutica, a dose de β-bloqueadores é ajustada até obtermos uma redução de 25% na frequência cardíaca (em repouso) ou inferior a 55 ppm ou desenvolvimento de sintomas.

Iniciar terapêutica farmacológica (β-bloqueadores) no Internamento.
Iniciar programa de profilaxia secundária de hipertensão portal (erradicaçãoendoscópica de varizes esofágicas) no Internamento (6ºdia) e agendar programa de erradicação de varizes gástricas.



21

Recomendação XII

Quando transferir o doente referenciado para endoscopia?

As recomendações do transporte inter-hospitalar aplicam-se a todas instituições independentemente do seu grau de diferenciação.

A transferência deve ser sempre individualizada tendo em consideração que:

1. O transporte não conduz a instabilidade para o doente com consequente agravamento do quadro clínico;
2. A unidade para onde o doente vai ser transportado possui os meios necessários para o seguimento clínico;
3. A sua transferência não vai alterar a terapêutica ou o prognóstico do doente.

RECOMENDAÇÕES Recursos

Uma Urgência Regional de Gastrenterologia pressupõe alguns princípios fundamentais:

- Estar preparada para a recepção de sangrantes graves a necessitarem de cuidados urgentes/emergentes/multidisciplinares (intensivos, medicina interna, cirurgia, radiologia de intervenção);
- A presença de um Gastroenterologista com treino diferenciado em Endoscopia de Urgência; um Centro de Endoscopia equipado;
- Um local onde monitorizar o sangrante antes e após o exame endoscópico;
- Unidades de Cuidados Intensivos /Intermédios onde alocar doentes instáveis ou com elevado potencial de recidiva hemorrágica.

- **Todos os doentes admitidos na urgência (da URGE) com HDA:**

➔ A estabilização hemodinâmica, a estratificação do risco clínico e a colocação de sonda naso-gástrica (de acordo com as recomendações contidas neste documento) sevem ser realizadas no serviço de urgência geral, sob pena de ocorrerem situações clínicas graves durante a espera do gastrenterologista;

➔Após a realização de endoscopia, observação e orientação pelo médico da URGE, os doentes internados que regressam ao serviço de urgência geral ficam sob a responsabilidade do clínico da respectiva área de internamento.

Excluem-se todos os doentes transferidos directamente pelos médicos da URGE.

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